

Mylan N.V.
Form 10-K
February 27, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the Fiscal Year Ended December 31, 2018

OR

Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from _____ to _____.

Commission file number 333-199861

MYLAN N.V.

(Exact name of registrant as specified in its charter)

The Netherlands

98-1189497

(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England

(Address of principal executive offices)

+44 (0) 1707-853-000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class: Name of Each Exchange on Which Registered:

Ordinary shares, nominal value €0.01 The NASDAQ Stock Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended

transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. "

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes " No

The aggregate market value of the outstanding ordinary shares, nominal value €0.01, of the registrant other than shares held by persons who may be deemed affiliates of the registrant, as of June 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$18,508,277,080.

The number of ordinary shares outstanding, nominal value €0.01, of the registrant as of February 22, 2019 was 515,949,946.

INCORPORATED BY REFERENCE

Document

An amendment to this Form 10-K will be filed no later than 120 days after the close of registrant's fiscal year.

Part of Form 10-K into
Which
Document is Incorporated
III

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MYLAN N.V.

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PART I

ITEM 1. Business

Mylan N.V. (the successor registrant to Mylan Inc.), along with its subsidiaries (collectively, the “Company,” “Mylan,” “our” or “we”), is a global pharmaceutical company committed to setting new standards in healthcare and providing 7 billion people access to high quality medicine. We offer a growing portfolio of more than 7,500 products, including prescription generic, branded generic, brand-name drugs and over-the-counter (“OTC”) remedies. We market our products in more than 165 countries and territories. As of December 31, 2018, our global workforce totaled approximately 35,000 employees and external contractors. Some of our employees are unionized or part of works councils or trade unions.

Transformation

Mylan was founded in 1961 as a privately-owned company to help people in rural communities in the United States (“U.S.”) state of West Virginia obtain quality affordable medicines. Originally a distributor of other firms’ products, we grew over time into one of the nation’s largest manufacturers of generic drugs (“Gx”). Mylan became a publicly traded company in 1973.

Approximately a decade ago, in response to industry changes, Mylan developed and began executing a transformation strategy. Our goal was to create a durable business model that would harness the power of competition to drive innovations capable of increasing access to medicine.

Our strategy involved creating robust research, manufacturing, supply chain and commercial platforms on a global scale; substantially expanding our portfolio of medicines; diversifying by geography, product type and channel; maintaining our commitment to quality; cultivating our corporate culture and workforce; and continuing to manage for the long-term.

Acquisitions, including that of Matrix Laboratories Limited (2007); Merck KGaA’s generics and specialty pharmaceutical business (2007); the EPD Business (as defined below) (2015) and Meda AB (publ.) (“Meda”) (2016), have played a significant role in our transformation. We continue to acquire complementary products and product-development capabilities. As part of our acquisition-integration efforts, Mylan has focused on how to best optimize and maximize all of our assets across the organization and all geographies.

Mylan N.V. was originally incorporated as a private limited liability company in the Netherlands in 2014. Mylan became a public limited liability company in the Netherlands through its acquisition of Abbott Laboratories’ non-U.S. developed markets specialty and branded generics (“Bx”) business (the “EPD Business”) on February 27, 2015. Mylan’s corporate seat is in the Netherlands; our principal executive offices are in England and our group’s global headquarters is in the U.S.

Unless otherwise indicated, industry data included in Item 1 is sourced from IQVIA Holdings Inc. and is for the twelve months ended November 2018. Mylan product information is from internal sources and is as of December 31, 2018.

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Business Model and Operations

Our mission is grounded in our conviction that every person should have the opportunity to live the healthiest life possible. For this reason, providing access to medicine is an important goal of our business model, pictured below.

OUR BUSINESS MODEL

To provide access, we seek to satisfy the needs of an incredibly diverse global pharmaceutical marketplace whose economic and political systems, approaches to delivering and paying for healthcare, languages and traditions, and customer and patient requirements vary by location and over time.

It is with these considerations in mind that we built and scaled our commercial, operational and scientific platforms, which we believe meet the evolving needs of customers in ways that are globally consistent and locally sensitive. As a result, Mylan now reaches patients with a wide range of products.

We believe that the breadth and depth - i.e., the diversity - of our business and platforms have rendered our business durable, as we are not dependent on any single market or product.

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We also believe that durability not only helps us expand people's access to medicine, it also allows us to better compete on a global basis than many of our peers. Our primary competitors in the prescription drugs space include other pharmaceutical companies, including manufacturers of brand-name, generic drug and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. Our OTC products face competition from pharmaceutical companies and from retailers that carry their own private-label brands.

DURABILITY COMPONENTS

We have structured our business and strive to operate it in ways that maximize our operational and financial results. Operationally, for instance, we have chosen to vertically integrate much of our manufacturing activity; this means producing many of our own active pharmaceutical ingredients ("APIs") and finished dosage forms. This approach affords us greater control over the cost and quality of what we make. All of the facilities discussed below are included in our reportable segments (North America, Europe, and Rest of World) primarily based on the location of the facility. Our principal administrative, research and development ("R&D") and manufacturing facilities are located around the world; many of the latter are strategically located in proximity to key markets.

In the U.S. and Puerto Rico, we own 16 manufacturing, distribution, and administrative facilities. Principal facilities include the group's global headquarters in Canonsburg, Pennsylvania; our campus in Morgantown, West Virginia, which includes an R&D center of excellence and manufacturing plant; and our distribution center in Greensboro, North Carolina.

Outside the U.S. and Puerto Rico, we own 39 production, distribution, and administrative facilities in 15 countries. In Europe, principal facilities include our principal executive offices in Hatfield, Hertfordshire, England; our global center in Dublin, Ireland; as well as key facilities in Ireland, Hungary, and France.

We also operate key facilities in India, Australia, and Japan. In India, principal facilities include our global center in Bangalore; an R&D center of excellence in Hyderabad; and several manufacturing plants located throughout the country.

Mylan also leases manufacturing, warehousing, distribution and administrative facilities in various locations, both within and outside of the U.S. Finally, Mylan relies upon many of our collaboration partners' manufacturing and other facilities throughout the world.

We believe all our facilities are in good operating condition, the machinery and equipment are well-maintained, the facilities are suitable for their intended purposes and they have capacities adequate for the current operations.

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The APIs and other materials and supplies we use in our manufacturing operations are purchased from third parties, and some are produced internally. Occasionally, however, resources we need are available from only a single supplier. Like many pharmaceutical companies, we supplement our production footprint through arrangements with other manufacturers.

Facilities and records related to our products are subject to periodic inspection by the U.S. Food and Drug Administration (the “FDA”), the European Medicines Agency (“EMA”), the Therapeutic Goods Administration in Australia and other authorities, as applicable. In addition, authorities often conduct pre-approval plant inspections to determine whether our systems and processes comply with current Good Manufacturing Practices (“cGMP”) and other regulations, and clinical-trial reviews to evaluate regulatory compliance and data integrity. Our suppliers, contract manufacturers, clinical trial partners and other business partners are subject to similar regulations and periodic inspections.

Moreover, as a part of our commitment to caring for the environment, we strive to comply in all material respects with applicable environmental laws and regulations. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not expected to have, a material adverse effect on our operations or competitive position.

Customers and Marketing

Our customers are essential in helping us create better health for a better world by making our products available to patients. Numbering in the tens of thousands, our customers include retail pharmacies; wholesalers and distributors; payers, insurers and governments; and institutions such as hospitals; among others. See “Channel Types” below for more information about our customers.

The table below displays the percentage of consolidated net sales to our largest customers during the years ended December 31, 2018, 2017 and 2016.

| | Percentage of Consolidated Net Sales | | |
|-------------------------------|--------------------------------------|------|------|
| | 2018 | 2017 | 2016 |
| McKesson Corporation | 12 % | 13 % | 16 % |
| AmerisourceBergen Corporation | 8 % | 8 % | 14 % |
| Cardinal Health, Inc. | 8 % | 10 % | 11 % |

In addition to being dynamic, the pharmaceutical industry is complex. How it functions, how it is regulated and how it provides patients access varies by location. Similarly, competition is affected by many factors. Examples of factors include innovation and development, timely approval of prescription drugs by health authorities, manufacturing capabilities, product quality, marketing effectiveness, portfolio size, customer service, consumer acceptance, product price, political stability and the availability of funding for healthcare.

Certain parts of our business also are affected by seasonality, e.g., due to the timing and severity of peak cough, cold and flu incidence, which can cause variability in sales trends for some of our products. While seasonality may affect quarterly comparisons within a fiscal year; it generally is not material to our annual consolidated results.

We serve our customers through a team of more than 7,000 sales and marketing professionals, all of whom are focused on establishing Mylan as our customers’ partner of choice. To best meet customers’ needs, Mylan manages its business on a geographic basis.

For these and other reasons, Mylan’s sales and marketing efforts vary accordingly by product, market and channel type, each of which is described below.

See the Application of Critical Accounting Policies section in Item 7 for more information related to customer arrangements.

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Product Types

Mylan markets prescription brand-name drugs; unbranded and branded prescription generic drugs; OTC products and APIs.

Brand-name drugs (“Rx”) typically are prescription pharmaceuticals that are sufficiently novel as to be protected by patents or other forms of exclusivity. As such, these drugs, which bear trade names, may be produced and sold only by those owning the rights, subject to certain challenges that other companies may make. Developing new medicines can take years and significant investment. Only a few promising therapies ever enter clinical trials. Fewer still are approved for sale by health authorities, at which point marketing to healthcare providers and consumers begins. Because patents and exclusivities last many years, they serve as an incentive to developers. During the periods protected, developers often recoup their investments and earn a profit. In many high-income countries, the brand business often is characterized by higher margins on lower volumes - especially as compared with generic manufacturers. We have acquired most of the branded products we offer.

Generic drugs are therapeutically equivalent versions of brand-name medicines. Generics generally become available once the patents and other exclusivities on their branded counterparts expire. Gx products typically are sold under their International Nonproprietary Names (“INNs”). INNs facilitate the identification of pharmaceutical substances or APIs. Each INN is unique and globally recognized. A nonproprietary name also is known as a generic name.

Mylan, like many other generic drugmakers, invests significant sums in R&D and in manufacturing capacity. We also often incur substantial litigation expense as a result of challenging brand patents or exclusivities. But because generic drugmakers are not required to reproduce expensive clinical trials and seldom engage in product promotion, Gx typically cost far less than branded drugs. The generics business is generally characterized by lower margins on higher volumes, as most generic drugmakers, Mylan included, offer a relatively large number of products.

Branded generics are off-patent products that are sold under an approved proprietary name for marketing purposes. Rx products often become Bx products once patent protections or other forms of exclusivity expire. Bx products are common in many countries outside the U.S., including emerging markets. In addition, complex products, such as biosimilars (that is, a biological product that is highly similar to an already approved reference biological product, and for which there are no

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clinically meaningful differences between the biosimilar and the reference biological product in terms of safety, purity and potency), often are marketed under a brand-name.

Rx and Bx products are more sensitive to promotion than are unbranded generic products. They therefore represent the focus of most of our sales representatives and product-level marketing activity.

OTC products are sold directly to consumers, without a prescription and without reimbursement. As with prescription medicines, properly approved OTC products are proven to be safe and effective when used as directed. OTC products also are subject to various regulatory requirements, including those applicable to manufacturing, advertising and promotion. OTC products may be sold under a brand-name or a molecule name.

Our API is sold through a dedicated sales and marketing team primarily to pharmaceutical companies throughout the world.

Market Types

Like other drug companies, Mylan focuses its sales and marketing efforts on the people who make key decisions around pharmaceutical prescribing, dispensing or buying. Decision-makers vary by country or region, reflecting law and custom, giving rise to different types of pharmaceutical markets. Many countries feature a mix of or hybrids of various market types, though Mylan may focus on just one type.

In prescription markets, physicians decide which medicines patients will take. Pharmacies then dispense the products as directed. Drug companies employ sales forces to educate doctors about the clinical benefits of their products. Representatives call on individual doctors or group practices; the process is known as detailing. Examples of countries served by Mylan that are mainly prescription markets are Japan, China, Russia, Turkey, Poland and Mexico.

In substitution markets, pharmacists generally are authorized (and in some cases required) by law to dispense an unbranded or branded generic, if available, in place of a brand-name medicine, or vice versa. Drug companies may use sales forces in these markets too, with representatives calling on and educating pharmacy personnel about their organization and products. Examples of countries served by Mylan that are mainly substitution markets are France, Italy, Spain, Portugal and Australia.

In tender markets, payers, such as governments or insurance companies, negotiate the lowest price for a drug (or group of drugs) on behalf of their constituents or members. In exchange, the chosen supplier's product is placed on the payer's formulary, or list of covered prescriptions. Often, a supplier's drug is the only one available in an entire class of drugs. Large sales forces are not needed to reach these decision-makers. Examples of generic markets served by Mylan that are mainly tender markets are Germany, New Zealand, Sweden and Denmark.

In distribution markets, retailers and wholesalers make drug-purchasing decisions. Large sales forces are not needed to reach the decision-makers representing these organizations. Note, however, that pharmacists operating in distribution markets also may be authorized to make substitution decisions when dispensing medicines. Examples of countries served by Mylan that are mainly distribution markets are the U.S., the United Kingdom ("U.K.") and Norway.

The allocation of our sales and marketing resources reflects the characteristics of these different market types.

In the case of OTC products, consumers are the decision-makers. OTC products are commonly sold via retail channels, such as pharmacies, drugstores and supermarkets. This makes their sale and marketing comparable to other retail businesses, with broad advertising and trade-channel promotion. Consumers often are loyal to well-known OTC brands. For this reason, suppliers of OTC products, Mylan included, must invest the time and resources needed to build strong OTC brand names.

Channel Types

Mylan's products make their way to patients through a variety of intermediaries, or channels.

Pharmaceutical wholesalers/distributors purchase prescription medicines and other medical products directly from manufacturers for storage in warehouses and distribution centers. The distributors then fill orders placed by healthcare providers and other authorized buyers.

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Pharmaceutical retailers purchase products directly from manufacturers or wholesalers/distributors. They then sell them to consumers in relatively small quantities for personal use.

Institutional pharmacies address the unique needs of hospitals, nursing homes and other such venues. Among the services provided are specialized packaging, such as unit-dose supply, for controlled administration.

Mail-order and e-commerce pharmacies receive prescriptions by mail, fax, phone or the internet at a central location; process them in large, mostly automated centers; and mail the drugs to the consumer.

Specialty pharmacies focus on managing the handling and service requirements associated with high-cost and more-complex drug therapies, such as those used to treat patients with rare or serious diseases.

Business Segments

Consistent with Mylan's focus on bringing its broad and diversified portfolio products to people in markets everywhere, the company reports results in three segments on a geographic basis as follows: North America, Europe and Rest of World.

Our North America segment comprises our operations in the U.S. and Canada. Our Europe segment encompasses our operations across 35 countries, including France, Italy, Germany, the U.K. and Spain. Our Rest of World segment reflects our operations in more than 120 countries outside of our North America and Europe segments.

The charts below display Mylan's net sales by segment and by product type for the year ended December 31, 2018. Net sales are generated primarily from the sale of pharmaceutical products, including API.

With respect to product type, generic offerings continue to represent 57% of our net sales, in keeping with Mylan's emphasis on expanding people's access to medicine.

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In addition, we have focused our products in 10 major therapeutic areas. We have critical mass in these areas, though our sales emphasis varies by market according to need and opportunity.

MYLAN'S MAJOR THERAPEUTIC AREAS*

| | | | | | |
|----------|----------------|--------------------|-------------|-----------------------|------------------|
| Products | Cardiovascular | CNS & Anesthesia | Dermatology | Diabetes & Metabolism | Gastroenterology |
| Current | 1,150 | 1,900 | 500 | 450 | 700 |
| Pipeline | 320 | 550 | 60 | 300 | 150 |
| Products | Immunology | Infectious Disease | Oncology | Respiratory & Allergy | Women's Health |
| Current | 80 | 1,100 | 450 | 600 | 650 |
| Pipeline | 100 | 900 | 550 | 150 | 150 |

*Product defined by product/dosage form/country. Products taken from internal data and rounded.

North America

Mylan's business in North America is driven mainly by our operations in the U.S., where we are one of the largest providers of prescription medicines. The U.S. pharmaceutical industry is very competitive, and the primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. We rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products.

Gx are widely accepted in the U.S., accounting in 2018 for approximately 90% of prescriptions dispensed, but only about 20% of total prescription drug costs. Over the last five years, Mylan has launched more generics in the U.S. than any other company.

Among our branded prescription products are EpiPen® Auto-Injector, Perforomist® Inhalation Solution and Dymista®. Also, we launched YUPELRI™, an inhalation solution for the maintenance treatment of patients with chronic obstructive pulmonary disease, in December 2018. Our OTC portfolio includes Cold-EEZE®, MidNite® and Vivarin®, as well as other products. Our promotion efforts are supported by a salesforce of approximately 400 sales representatives.

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New product launches are an important growth driver. Important recent launches include complex products such as Wixela™ Inhub™ (generic Advair Diskus®) in February 2019, Glatiramer Acetate Injection (generic Copaxone®), Fulphila™ (biosimilar to Neulasta®) and generic ESTRACE®. Our emphasis on complex products, some of which we develop in collaboration with other companies, is evidenced by, to name a few of relevance in the U.S., our efforts to introduce generic versions of Symbicort®, Restasis®, EYLEA® and the biosimilar to Herceptin®.

While our U.S. customer base is extensive, it increasingly comprises a small number of very large firms, as the pharmaceutical industry continues to undergo tremendous change and consolidation. Mylan is well positioned to serve such customers - in the U.S. and elsewhere - due to the scale we have built in terms of R&D, API and finished-dosage-form manufacturing, and portfolio breadth.

Europe

Mylan's business in Europe is driven by our scale across 35 countries.

Generic medicines have transformed healthcare in the region over the last decade by significantly increasing patients' access to medicine in an era of rising demand for healthcare services and constrained finances. In 2018 generic pharmaceuticals represented more than half of medicines used in Europe, but less than one quarter of total drug costs. Europe represents the world's second largest generic pharmaceuticals market, by value. The European markets, where many governments provide healthcare at a low direct cost to consumers and regulate pharmaceutical prices or patient reimbursement levels, continue to be highly competitive, especially in terms of pricing, quality standards, service levels and product portfolio. Our leadership position in a number of countries provides us a platform to fulfill the needs of patients, physicians, pharmacies, customers and payors.

Among our many branded prescription products are Creon®, Influvac® and Dymista®. Our OTC portfolio includes Brufen®, CB12® and EndWarts®, as well as other products. Our promotional efforts in the region are supported by approximately 2,500 sales representatives.

New product launches are an important growth driver. Our focus on complex products is evidenced by our ability to gain approval for products such as Hulio™ (adalimumab), Glatiramer Acetate, Semglee™, our insulin glargine, and Ogivri™ (trastuzumab-dkst). In addition we remain focused on introducing additional biosimilars like Fulphila™ (pegfilgrastim) and rituximab.

We expect Mylan's business in Europe to keep benefiting from our commercial platform, through which we simultaneously can serve multiple market types through multiple channels. Doing so allows us to focus on maximizing returns on investment by, for instance, repurposing branded drugs that lose exclusivity as tender or substitution products, or by switching from one proven strategy to another as individual government policies evolve, as is currently the case for biosimilars.

We look to maintain our leadership positions in markets such as France and Italy and prioritize opportunities in additional markets, such as Germany, Spain and the U.K.

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Rest of World

Mylan's commercial operations in Rest of World comprise a diverse group of businesses, many of which we believe have high growth potential. The Rest of World markets are attractive because of the growing middle class within these countries combined with an increase in the demand for pharmaceutical products. The highly competitive environment includes conditions like pricing and market access challenges, potential political instability, significant currency fluctuations and limited or changing availability of funding for healthcare.

Mylan's focus on becoming a leader in supplying antiretroviral medicines ("ARVs") to treat HIV/AIDS has helped to increase our presence in many emerging market countries over the last decade.

Today approximately 40% of people being treated worldwide for the disease, as well as approximately 60% of the world's HIV+ children, rely on one of our products. Most of these individuals live in countries that make up our Rest of World segment.

Many countries in this segment are brand-focused, and generic penetration is low. Our more than 2,000 sales representatives are deployed in approximately 35 countries to promote our products. Among them are brands such as Amitiza®, Dona®, Creon®, Elidel® and Legalon®.

New product launches are an important growth driver. In accordance with our focus on complex products, we look forward to continuing to launch products such as Semglee™, ABEVMY® (bevacizumab) and Ogi™ (trastuzumab-dkst) into additional countries, and introducing new medicines.

We look to maintain our leadership positions in countries such as Australia and Japan. We also are focused on maximizing opportunities in emerging markets like China, Brazil, India, Russia, Mexico, Turkey and Southeast Asia, where we see opportunity to introduce our existing global portfolio of products, especially our generics.

In addition, we have begun leveraging our ARV platform and expertise to help HIV patients in higher-income countries, and to expand access to treatments for other infectious diseases, such as tuberculosis and malaria.

Refer to Note 14 Segment Information included in Item 8 in this Annual Report on Form 10-K for more information about our segments.

Government Regulation

Regulation by governmental authorities is a significant factor in the R&D, manufacture, marketing, sales and distribution of pharmaceuticals. Human therapeutic products are subject to rigorous preclinical and clinical testing to gather data to support approval, which requires extensive data and information; manufacturing is conducted under exacting conditions governed by extensive regulation; and post-approval activities, such as advertising and promotion and pharmacovigilance, are subject to pervasive regulation.

The lengthy process of developing products and obtaining required approvals and the continuing need for post-approval compliance with applicable statutes and regulations, require the expenditure of substantial resources.

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approval, if and when obtained, may be limited in scope. Further, approved drugs, as well as their manufacturers, are subject to ongoing post-marketing review and inspection, which can lead to the discovery of previously unknown problems with products or the manufacturing or quality control procedures used in their production, which may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

Any failure or delay by us, our suppliers of manufactured drug product, collaborators or licensees, in obtaining regulatory approvals could adversely affect the marketing of our products and our ability to receive product revenue, license revenue or profit-sharing payments.

Other Regulatory Requirements

Our business is subject to a wide range of various other federal, state, non-governmental, and local agency rules and regulations. They focus on fraud and corruption, pricing and reimbursement, data privacy, and the environment, among many other considerations. For more information about certain of these regulations and the associated risks we face, see Item 1A. Risk Factors.

Research and Development

Mylan has a globally integrated R&D platform that is fueling our growth by filling our pipeline. We believe R&D always has been one of Mylan's core strengths. Our Scientific Affairs team, which includes researchers and regulatory and clinical experts, numbers more than 3,000 people who work collaboratively across our 12 different R&D centers around the world, including 10 technology-focused development sites and 2 global R&D centers.

Consistent with Mylan's drive for durability, the allocation of our investments over the last several years has shifted away from commodity products, such as conventional oral solid dosage ("OSD") forms, to more complex or difficult-to-formulate products, such as biosimilars.

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As a result, our product pipeline includes a variety of dosage forms. Collectively, these investments represent more than 3,600 products under development or pending approval around the world. Refer to the chart in the Business Segments section above for information pertaining to products in pipeline by major therapeutic area.

Collaboration and Licensing Agreements

We periodically enter into collaboration and licensing agreements with other companies to develop, manufacture, market and/or sell pharmaceutical products. Doing so helps us share risks and costs, leverage strengths and scale up commercialization. The result often is that medicines become available sooner and to a significantly larger group of patients.

Our significant agreements are primarily focused on the development, manufacture, supply and commercialization of multiple, high-value biosimilar compounds, insulin analog products and respiratory products. Mylan's significant collaboration and licensing agreements include those with Pfizer Inc. ("Pfizer"), Momenta Pharmaceuticals, Inc. ("Momenta"), Theravance Biopharma, Inc. ("Theravance Biopharma"), Biocon Ltd. ("Biocon") and Fujifilm Kyowa Kirin Biologics Co. Ltd. Refer to Note 18 Collaboration and Licensing Agreements included in Item 8 in this Annual Report on Form 10-K for more information.

Intellectual Property

Mylan considers the protection of our intellectual property rights to be extremely valuable, and we act to protect them from infringement by third parties.

We have an extensive trademark portfolio and routinely apply to register key brand-name, generic, branded generic, biosimilars and OTC trade names in numerous countries around the world. Our registered trademarks are renewable indefinitely, and these registrations are properly maintained in accordance with the laws of the countries in which they are registered.

We also have an extensive patent portfolio and actively file for patent protection in various countries to protect our brand-name, generic, branded generic, biosimilars and OTC products, including processes for making and using them. We have more than 4,500 patents filed globally. For additional information, see "Risk Factors - We rely on the effectiveness of our patents, confidentiality agreements and other measures to protect our intellectual property rights." Further, we have well-established safeguards in place to protect our proprietary know-how and trade secrets, both of which we consider extremely valuable to our intellectual property portfolio.

We look for intellectual property licensing opportunities to or from third parties, related not only to our existing products, but as a means for expanding our product portfolio.

We rely on the aforementioned types of intellectual property, as well as our copyrights, regulatory exclusivities and contractual protections, to establish a broad scope of intellectual property rights for our product portfolio.

Exchange Act Reports

Mylan maintains a website at Mylan.com. We make available on or through it certain reports and associated amendments that the Company files with the Securities and Exchange Commission ("SEC") in accordance with the Securities Exchange Act of 1934 ("Exchange Act"). Filings include our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports.

We make this information available on our website free of charge, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The contents of our website are not incorporated by reference in this Annual Report on Form 10-K and shall not be deemed "filed" under the Exchange Act.

The SEC also maintains a website (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

ITEM 1A. Risk Factors

We operate in a complex and rapidly changing environment that involves risks, many of which are beyond our control. Our business, financial condition, results of operations, cash flows, and/or share price could be materially affected by any of these

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risks, if they occur, or by other factors not currently known to us, or not currently considered to be material. These risk factors should be read in conjunction with the other information in this Annual Report on Form 10-K, as well as our other filings with the SEC.

Our risk factors are organized into four categories: Strategic, Operational, Compliance and Finance.

Strategic Risks

We do not anticipate paying dividends for the foreseeable future, and our shareholders must rely on increases in the trading price of our ordinary shares to obtain a return on their investment.

Mylan N.V. does not anticipate paying dividends in the immediate future. We anticipate that we will retain all earnings, if any, to support our operations and to opportunistically pursue additional transactions to deliver additional shareholder value. Any future determination as to the payment of dividends will, subject to Dutch law requirements, be at the sole discretion of our board of directors and will depend on our financial position, results of operations, capital requirements, and other factors our board of directors deems relevant at that time. Holders of Mylan N.V.'s ordinary shares must rely on increases in the trading price of their shares to obtain a return on their investment in the foreseeable future.

The market price of our ordinary shares may be volatile, and the value of your investment could materially decline. Investors who hold Mylan N.V.'s ordinary shares may not be able to sell their shares at or above the price at which they purchased such shares. The share price of Mylan N.V.'s ordinary shares fluctuates materially from time to time, including a significant decline throughout 2018, and we cannot predict the price of our ordinary shares at any given time. The risks described herein could cause the price of our ordinary shares to fluctuate materially. In addition, the stock market in general, including the market for pharmaceutical companies, has experienced price and volume fluctuations. These broad market and industry factors may materially harm the market price of our ordinary shares, regardless of our operating performance. In addition, the price of our ordinary shares may be affected by the valuations and recommendations of the analysts who cover us, and if our results do not meet the analysts' forecasts and expectations, the price of our ordinary shares could decline as a result of analysts lowering their valuations and recommendations or otherwise. In the past, following periods of volatility in the market and/or in the price of a company's stock, securities class-action litigation has been instituted against us and other companies. Such litigation could result in substantial costs and diversion of management's attention and resources, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price. We or our shareholders also may offer or sell our ordinary shares or securities convertible into or exchangeable or exercisable for ordinary shares. An increase in the number of ordinary shares issued and outstanding and the possibility of sales of ordinary shares or securities convertible into or exchangeable or exercisable for ordinary shares may depress the future trading price of our ordinary shares. In addition, if additional offerings occur, the voting power of our then existing shareholders may be diluted.

Our strategic initiatives may not achieve all intended benefits.

There can be no assurance that our strategic initiatives will achieve their intended effects. We continually evaluate various strategic transactions and business arrangements, including acquisitions, asset purchases, partnerships, joint ventures, restructurings, divestitures, investments, market selection and market strategy on an ongoing basis. These transactions and arrangements may be material both from a strategic and financial perspective. There can be no assurance that we will be able to successfully complete the integration of acquired businesses or assets with Mylan, or otherwise fully realize the expected benefits of any transactions or restructurings. Furthermore, although our expectation is to engage in asset sales only if they advance or otherwise support our overall strategy, any such sale could reduce the size or scope of our business, our market share in particular markets or our opportunities with respect to certain markets, products or therapeutic categories.

The difficulties of achieving the benefits of strategic initiatives include, among others:

- the diversion of management's attention to integration matters and restructuring activities;
- difficulties in achieving anticipated synergies, operating efficiencies, business opportunities, and growth prospects from restructurings or business or asset combinations within the expected timeframe or at all;

difficulties in the integration of operations and information technology (“IT”) applications, including enterprise resource planning (“ERP”) systems;
difficulties in the integration of employees;
difficulties in managing the operations of a larger or more complex company;

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- challenges in keeping existing customers and obtaining new customers;
- challenges in reducing reliance on transition services prior to the expiration of any period in which such services are provided by a transaction counterparty;
- difficulties in obtaining a favorable price for any divestiture, in a timely manner or at all;
- challenges in moving production facilities, including obtaining the consent of customers or regulatory authorities;
- operational or financial difficulties that would not have occurred if acquired companies, businesses, or assets continued operating in their former structures;
- challenges in attracting and retaining key personnel; and
- the complexities of managing relationships with transaction counterparties and other business partners, including service agreements, development and manufacturing relationships, and license arrangements.

The overall execution of a strategic initiative, including the integration of a business or asset or restructuring activities, may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customer relationships, and diversion of management's attention, among other potential adverse consequences, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

We may be adversely affected by significant scrutiny from third parties, including governments, or negative publicity with respect to matters relating to our products, pricing practices and other matters.

The Company has been subject to significant press coverage and scrutiny from third parties, including regulators, legislative bodies and enforcement agencies, with respect to matters relating to our business, pricing practices, and other matters. This coverage and public scrutiny have included assertions of wrongdoing against the Company which, regardless of the factual or legal basis for such assertions, have resulted in, and may continue to result in, investigations, and calls for investigations, by governmental agencies at both the federal and state levels, claims brought against the Company by governmental agencies or private parties, and regulators taking other measures that could have a negative effect on the Company's business. For example, both the U.S. House of Representatives and the U.S. Senate have conducted hearings with respect to pharmaceutical drug pricing practices and alleged anti-competitive behavior by pharmaceutical companies, and additional hearings are scheduled. Ongoing focus on these issues has in the past led and in the future could lead to investigations of price increases and other business practices of specific pharmaceutical companies, including Mylan. It is not possible to predict the ultimate outcome of any such investigations or claims or what other investigations or lawsuits or regulatory responses may result from such assertions.

There has also recently been intense publicity regarding the pricing of pharmaceuticals more generally, including publicity and pressure resulting from prices charged by competitors and peer companies for new products as well as price increases by competitors and peer companies on older products that some have deemed excessive. We have experienced and may continue to experience downward pricing pressure on the price of certain of our products due to social or political pressure to lower the cost of drugs, which could reduce our revenue and future profitability.

Any of the above developments could result in reputational harm and reduced market acceptance and demand for our products, could harm our ability to market our products in the future, could cause us to incur significant expense, could cause our senior management to be distracted from execution of our business strategy, and could have a material adverse effect on our business, reputation, financial condition, results of operations, cash flows and/or ordinary share price.

We have and may continue to experience pressure on the pricing of and reimbursements for certain of our products due to consolidation among purchasers or social and political pressure to lower the cost of drugs.

We operate in a challenging environment, with significant pressures on the pricing of our products and on our ability to obtain and maintain satisfactory rates of reimbursement for our products by governments, insurers and other payors. The growth of overall healthcare costs has led governments and payors to implement new measures to control healthcare spending. As a result, we face numerous cost-containment measures by governments and other payors, including certain government-imposed industry-wide price reductions, mandatory pricing systems, reference pricing systems, tender systems, shifting of the payment burden to patients through higher co-payments, and requirements for

increased transparency on pricing. In the U.S., certain of these pressures are further compounded by increasing consolidation among wholesalers, retailer drug chains, pharmacy benefit managers (“PBMs”), private insurers, managed care organizations and other private payors, which can increase their negotiating power, particularly with respect to our generic drugs. Please also refer to “A significant portion of our revenues is derived from sales to a limited number of customers.”

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There has also been increasing U.S. federal and state legislative and enforcement interest with respect to drug pricing. In particular, U.S. federal prosecutors have issued subpoenas to pharmaceutical companies, including Mylan, seeking information about their drug pricing practices, among other issues, and members of the Congress have sought information from certain pharmaceutical companies, including Mylan, relating to drug-price increases.

In addition, there has been legislation and legislative proposals concerning drug prices and related issues, including the perceived need to bring more transparency to drug pricing, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs. For example, California, Oregon and several other states have recently implemented legislation requiring pharmaceutical companies to provide greater transparency with respect to drug prices and price increases and other states are considering similar legislation. This type of legislation, at the federal or state level, could affect demand for, or pricing of, our products and we cannot predict what, if any, additional legislative developments may transpire or what the ultimate impact may be.

Any of the events or developments described above could have a material adverse impact on our business, reputation, financial condition, results of operations, cash flows and/or ordinary share price.

Current and changing economic conditions may adversely affect our industry, business, partners and suppliers.

The global economy continues to experience significant volatility, and the economic environment may become less favorable. Economic volatility, governmental financial restructuring efforts and evolving deficit and spending reduction programs could negatively impact the global economy and the pharmaceutical industry. This has led, or could lead, to reduced consumer and customer spending, reduced or eliminated governmental or third-party payor coverage or reimbursement or reduced spending on healthcare, including but not limited to pharmaceutical products.

While generic drugs present an alternative to higher-priced branded products, our sales could be negatively impacted if patients forego obtaining healthcare, patients and customers reduce spending or purchases, or if governments or third-party payors reduce or eliminate coverage or reimbursement amounts for pharmaceuticals or impose price or other controls adversely impacting the price or availability of pharmaceuticals. In addition, reduced consumer and customer spending, reduced government or third-party payor coverage or reimbursement, or new government controls, may drive us and our competitors to decrease prices, may reduce the ability of customers to pay, or may result in reduced demand for our products. The occurrence of any of these risks could have a material adverse effect on our industry, business, financial condition, results of operations, cash flows, and/or ordinary share price.

We have significant operations globally, which exposes us to the risks inherent in conducting our business internationally.

Our operations extend to numerous countries outside the U.S., including our significant operations in India, and are subject to the risks inherent in conducting business globally and under the laws, regulations, and customs of various jurisdictions. These risks include, but are not limited to:

- compliance with the national and local laws of countries in which we do business, including, but not limited to, data privacy and protection, import/export and intellectual property protections;
- less established legal and regulatory regimes in certain jurisdictions;
- compliance with a variety of U.S. laws including, but not limited to, regulations put forth by the U.S. Treasury's Office of Foreign Assets Control, the Iran Threat Reduction and Syria Human Rights Act of 2012 and rules relating to the use of certain "conflict minerals" under Section 1502 of the Dodd-Frank Wall Street Reform and the Consumer Protection Act;
- changes in laws, regulations, and practices affecting the pharmaceutical industry and the healthcare system, including but not limited to imports, exports, manufacturing, quality, cost, pricing, reimbursement, approval, inspection, and delivery of healthcare;
- changes in policies designed to promote foreign investment, including significant tax incentives, liberalized import and export duties, and preferential rules on foreign investment and repatriation;
- differing local product preferences and product requirements;
- adverse changes in the economies in which we or our partners and suppliers operate as a result of a slowdown in overall growth, a change in government or economic policies, or financial, political, or social change or instability in

such countries that affects the markets in which we operate, particularly emerging markets;
• changes in employment laws, wage increases, or rising inflation in the countries in which we or our partners and suppliers operate;
• supply disruptions and increases in energy and transportation costs;

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- increased tariffs on the import or export of our products or API, including on imports from China to the U.S.;
- natural or man-made disasters, including droughts, floods, earthquakes, hurricanes and the impact of climate change in the countries in which we or our partners and suppliers operate;
- local disturbances, terrorist attacks, riots, social disruption, wars, or regional hostilities in the countries in which we or our partners and suppliers operate and that could affect the economy, our operations and employees by disrupting operations and communications, making travel and the conduct of our business more difficult, and/or causing our customers to be concerned about our ability to meet their needs; and
- government uncertainty, including as a result of new or changed laws and regulations.

We also face the risk that some of our competitors have more experience with operations in such countries or with international operations generally and may be able to manage unexpected crises more easily. Moreover, the internal political stability of, or the relationship between, any country or countries where we conduct business operations may deteriorate. Changes in a country's political stability or the state of relations between any such countries are difficult to predict and the political or social stability in and/or diplomatic relations between any countries in which we or our partners and suppliers do business could meaningfully deteriorate.

For example, the formal change in the relationship between the European Union ("EU") and the U.K. as a result of the U.K. referendum to leave the EU ("Brexit") could impact our business. Whether Brexit occurs, as well as its exact structure and timing, are still being negotiated and therefore the impact remains uncertain. However, in the event Brexit occurs, it could lead to divergent national laws and regulations, import/export restrictions, and potential changes to intellectual property rights, regulatory approval requirements and pharmaceutical regulations in the EU and the U.K., which could materially impact the way we conduct our operations in those markets. In addition, because we are tax resident in the U.K., the U.K. withdrawal from the EU could, depending on the results of the ongoing negotiations, eliminate the benefit of certain tax treaties and tax-related EU directives, which could have a material adverse effect on our tax position by, among other effects, subjecting us to withholding taxes on certain intercompany transactions. It may be time-consuming and expensive for us to alter our internal operations in order to comply with such new or changing regulations or tax treatments. Any of these effects of Brexit, and others we cannot anticipate, could negatively affect our business and financial results.

The occurrence of any one or more of the above risks could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

Charges to earnings resulting from acquisitions could have a material adverse effect on our business, financial condition, results of operations, cash flows and/or ordinary share price.

Under accounting principles generally accepted in the U.S. ("U.S. GAAP") relating to business acquisition accounting standards, we recognize the identifiable assets acquired, the liabilities assumed, and any noncontrolling interests in acquired companies generally at their acquisition date fair values and, in each case, separately from goodwill.

Goodwill as of the acquisition date is measured as the excess amount of consideration transferred, which is also generally measured at fair value, and the net of the acquisition date amounts of the identifiable assets acquired and the liabilities assumed. Our estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain. After we complete an acquisition, the following factors could result in material charges and adversely affect our operating results and may adversely affect our cash flows:

- costs incurred to combine the operations of companies we acquire, such as transitional employee expenses and employee retention, redeployment or relocation expenses;
- impairment of goodwill or intangible assets, including acquired in-process research and development ("IPR&D");
- amortization of intangible assets acquired;
- a reduction in the useful lives of intangible assets acquired;
- identification of or changes to assumed contingent liabilities, including, but not limited to, contingent purchase price consideration including fair value adjustments, income tax contingencies and other non-income tax contingencies, after our final determination of the amounts for these contingencies or the conclusion of the measurement period (generally up to one year from the acquisition date), whichever comes first;

charges to our operating results to eliminate certain duplicative pre-acquisition activities, to restructure our operations or to reduce our cost structure; and
charges to our operating results resulting from expenses incurred to effect the acquisition.

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A significant portion of these adjustments could be accounted for as expenses that will decrease our net income and earnings per share for the periods in which those costs are incurred.

In particular, the amount of goodwill and identifiable intangible assets on our consolidated balance sheets is significant as a result of our acquisitions and other transactions, and may increase further following future potential acquisitions, and we may, from time to time, sell assets that we determine are not critical to our strategy or execution. Future events or decisions may also lead to asset impairments and/or related charges. Certain non-cash impairments may result from a change in our strategic goals, business direction or other factors relating to the overall business environment.

Any such charges could cause a material adverse effect on our business, financial condition, results of operations, cash flows, shareholders' equity and/or ordinary share price.

The illegal distribution and sale by third parties of counterfeit versions of our products or of diverted or stolen products could have a negative impact on our reputation and our business.

The pharmaceutical drug supply has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products that do not meet the rigorous manufacturing and testing standards that our products undergo. Counterfeit products are frequently unsafe or ineffective and can be potentially life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of API or no API at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product. It is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. In addition, unauthorized diversions of products or thefts of inventory at warehouses, plants, or while in-transit, which are not properly stored, or which are sold through unauthorized channels, could adversely impact patient safety, our reputation, and our business.

Public loss of confidence in the integrity of pharmaceutical products as a result of counterfeiting, diversion, or theft could have a material adverse effect on our business, reputation, financial condition, results of operations, cash flows, and/or ordinary share price.

We face vigorous competition that threatens the commercial acceptance and pricing of our products.

The pharmaceutical industry is highly competitive. We face competition from other pharmaceutical manufacturers globally, some of whom are significantly larger than we are. Our competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including but not limited to the possibility that they may have:

- proprietary processes or delivery systems;
- larger or more productive R&D and marketing staff;
- larger or more efficient production capabilities in a particular therapeutic area;
- more experience in preclinical testing and human clinical trials;
- more products; or
- more experience in developing new drugs and greater financial resources, particularly with regard to manufacturers of branded products.

We also face increasing competition from lower-cost generic products and other branded products. Certain of our products are not protected by patent rights or have limited patent life and will soon lose patent protection. Loss of patent protection for a product typically is followed promptly by the introduction of generic substitutes. As a result, sales of many of these products may decline or stop growing over time. Various factors may result in the sales of certain of our products declining faster than has been projected. In addition, legislative proposals emerge from time to time in various jurisdictions to further encourage the early and rapid approval of generic drugs. Any such proposal that is enacted into law could increase competition and worsen this negative effect on our sales.

Competitors' products may also be safer, more effective, more effectively marketed or sold, or have lower prices or better performance features than ours. We cannot predict with certainty the timing or impact of competitors' products.

PBMs and other

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pharmaceutical manufacturers may utilize contracting strategies that could decrease generic utilization and negatively impact our products. In addition, our sales may suffer as a result of changes in consumer demand for our products, including those related to fluctuations in consumer buying patterns tied to seasonality, importation by consumers or the introduction of new products by competitors.

The occurrence of any of the above risks could have an adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

A relatively small group of products may represent a significant portion of our revenues, net sales, gross profit, or net earnings from time to time.

Sales of a limited number of our products from time to time represent a significant portion of our revenues, net sales, gross profit, and net earnings. For the years ended December 31, 2018 and 2017, Mylan's top ten products in terms of sales, in the aggregate, represented approximately 20% and 21%, respectively, of the Company's net sales. If the volume or pricing of our largest selling products declines in the future, our business, financial condition, results of operations, cash flows, and/or ordinary share price could be materially adversely affected.

Our business could be negatively affected by the performance of our third-party collaboration partners.

We have entered into strategic alliances with partners to develop, manufacture, market and/or distribute certain products, and/or certain components of our products, in various markets. We commit substantial effort, funds and other resources to these various collaborations, including with respect to the development of biosimilar products. There is a risk that the investments made by us in these collaborative arrangements will not generate financial returns. While we believe our relationships with our partners generally are successful, disputes or conflicting priorities and regulatory or legal intervention could be a source of delay or uncertainty as to the expected benefits of the collaboration. In addition, we enter into agreements with our collaboration partners that provide for certain services, as well as cross manufacturing, development and licensing arrangements. A failure or inability of our partners to fulfill their collaboration obligations, or the occurrence of any of the risks above, could have an adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

We may experience reductions in the levels of reimbursement for pharmaceutical products by governmental authorities, health maintenance organizations ("HMOs"), or other third-party payors. In addition, the use of tender systems and other forms of price control, including legislative or regulatory programs impacting pharmaceutical prices, could reduce prices for our products or reduce our market opportunities.

Various governmental authorities (including, among others, the U.K. National Health Service and the German statutory health insurance scheme) and private health insurers and other organizations, such as HMOs in the U.S., provide reimbursements or subsidies to consumers for the cost of certain pharmaceutical products. Demand for our products depends in part on the extent to which such reimbursement is available. In the U.S., third-party payors increasingly challenge the pricing of pharmaceutical products. These trends and other trends toward the growth of HMOs, managed healthcare, and legislative healthcare reform create significant uncertainties regarding the future levels of reimbursement for pharmaceutical products. Further, any reimbursement may be reduced in the future to the point that market demand for our products and/or our profitability declines. Such a decline could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price. In addition, current or future U.S. federal, U.S. state or other countries' laws and regulations may influence the prices of drugs and, therefore, could adversely affect the payments we receive for our products. For example, existing programs in certain U.S. states seek to broadly set prices within those states through the regulation and administration of the sale of prescription drugs. Expansion of these programs, and, in particular, changes to state Medicare and/or Medicaid programs, or changes required in the way in which Medicare payment rates are set and/or the way Medicaid rebates are calculated, could adversely affect the payment we receive for our products. In order to control expenditure on pharmaceuticals, most member states in the EU regulate the pricing of products and, in some cases, limit the range of different forms of pharmaceuticals available for prescription by national health services. These controls can result in considerable price differences between member states.

Several countries in which we operate have implemented, or plan to or may implement, government mandated price reductions and/or other controls. When such price controls occur, pharmaceutical companies have generally

experienced significant declines in revenues and profitability and uncertainties continue to exist within the market after the price decrease. Such price reductions or controls could have an adverse effect on our business, and as uncertainties are resolved or if other countries in which we operate enact similar measures, they could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

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A number of markets in which we operate have also implemented or may implement tender systems for generic pharmaceuticals in an effort to lower prices. Under such tender systems, manufacturers submit bids which establish prices for generic pharmaceutical products. Upon winning the tender, the winning company will receive a preferential reimbursement for a period of time. The tender system often results in companies underbidding one another by proposing low pricing in order to win the tender. Other markets may also consider the implementation of a tender system or other forms of price controls. Even if a tender system is ultimately not implemented, the anticipation of such could result in price reductions.

Failing to win tenders, or the implementation of similar systems or other forms of price controls in other markets leading to further price declines, could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

Healthcare reform legislation could have a material adverse effect on our business.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for, healthcare services in the U.S., and it is likely that Congress and state legislatures and health agencies will continue to focus on healthcare reform in the future. The Patient Protection and Affordable Care Act (“PPACA”) and The Health Care and Education and Reconciliation Act of 2010 (H.R. 4872), which amends the PPACA (collectively, the “Health Reform Laws”), were signed into law in March 2010. While the Health Reform Laws may increase the number of patients who have insurance coverage for our products, they also include provisions such as the assessment of a pharmaceutical manufacturer fee and an increase in the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs.

We are unable to predict the future course of federal or state healthcare legislation. The Health Reform Laws and further changes in the law or regulatory framework that reduce our revenues or increase our costs could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

Additionally, we encounter similar regulatory and legislative issues in most other countries. In the EU and some other international markets, the government provides healthcare at low cost to consumers and regulates pharmaceutical prices, patient eligibility and/or reimbursement levels to control costs for the government-sponsored healthcare system. These systems of price regulations may lead to inconsistent and lower prices. Within the EU and in other countries, the availability of our products in some markets at lower prices undermines our sales in other markets with higher prices. Additionally, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may also impair our ability to obtain acceptable prices in existing and potential new markets, and may create the opportunity for third party cross border trade.

Significant additional reforms to the U.S. healthcare system, or to the healthcare systems of other markets in which we operate, could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

Provisions in our governance arrangements or that are otherwise available under Dutch law could discourage, delay, or prevent a change in control of us and may affect the market price of our ordinary shares.

Some provisions of our governance arrangements that are available under Dutch law, such as our grant to a Dutch foundation (stichting) of a call option to acquire preferred shares to safeguard the interests of the Company, its businesses and its stakeholders against threats to our strategy, mission, independence, continuity and/or identity, may discourage, delay, or prevent a change in control of us, even if such a change in control is sought by our shareholders. An inability to effectively deal with and respond to unsolicited business proposals could limit our future growth and have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

We have in the past and may in the future receive proposals to acquire all of our outstanding shares or similar unsolicited business proposals. Such unsolicited business proposals may not be consistent with or enhancing to our financial, operational, or market strategies and may not further the interests of our shareholders and other stakeholders, including employees, creditors, customers, suppliers, relevant patient populations and communities in

which Mylan operates and may jeopardize the sustainable success of Mylan's business. However, the evaluation of and response to such unsolicited business proposals may nevertheless distract management and/or disrupt our ongoing businesses, which may adversely affect our relationships with customers, employees, partners, suppliers, regulators, and others with whom we have business or other dealings.

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The expansion of social media platforms presents new risks and challenges.

To the extent that we seek to use social media tools as a means to communicate about our products and/or business, there are uncertainties as to the rules that apply to such communications, or as to the interpretations that authorities will apply to the rules that exist. As a result, despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that our use of social media for such purposes may cause us to be found in violation of them. Our employees may knowingly or inadvertently make use of social media tools in ways that may not be aligned with our social media strategy, may give rise to liability, or could lead to the loss of material non-public information, trade secrets or other intellectual property, or public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others. In addition, negative posts or comments about us on any social media website could damage our reputation. Any of the above risks could have a material adverse effect on our business, reputation, financial condition, results of operations, cash flows, and/or ordinary share price.

Operational Risks

Our failure to comply with applicable environmental and occupational health and safety laws and regulations worldwide could adversely impact our business, financial condition, results of operations, cash flows, and/or ordinary share price.

We are subject to various U.S. federal, state, and local and non-U.S. laws and regulations concerning, among other things, the environment, climate change, regulation of chemicals, employee safety and product safety. These requirements include regulation of the handling, manufacture, transportation, storage, use and disposal of materials, including the discharge of hazardous materials and pollutants into the environment. In the normal course of our business, we are exposed to risks relating to possible releases of hazardous substances into the environment, which could cause environmental or property damage or personal injuries, and which could result in (i) our noncompliance with such environmental and occupational health and safety laws and regulations and (ii) regulatory enforcement actions or claims for personal injury and property damage against us. If an unapproved or illegal environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. The substantial unexpected costs we may incur could have a material and adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price. In addition, our environmental capital expenditures and costs for environmental compliance may increase substantially in the future as a result of changes in environmental laws and regulations, the development and manufacturing of a new product or increased development or manufacturing activities at any of our facilities. We may be required to expend significant funds and our manufacturing activities could be delayed or suspended, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

The pharmaceutical industry is heavily regulated, and we face significant costs and uncertainties associated with our efforts to comply with applicable laws and regulations.

The pharmaceutical industry is subject to regulation by various governmental authorities. For instance, we must comply with applicable laws and requirements of the FDA and other regulatory agencies, including foreign authorities, in our other markets with respect to the research, development, manufacture, quality, safety, effectiveness, approval, labeling, tracking, tracing, authentication, storage, record-keeping, reporting, pharmacovigilance, sale, distribution, import, export, marketing, advertising, and promotion of pharmaceutical products. We are committed to conducting our business, including the sales and marketing of our products, in compliance with all applicable laws and regulations. These laws and regulations, however, are numerous and complex and it is possible that a governmental authority may challenge our activities, or that an employee or agent could violate these laws and regulations without our knowledge. Failure to comply with regulations of the FDA and other U.S. and foreign regulators could result in a range of consequences, including, but not limited to, fines, penalties, disgorgement, unanticipated compliance expenditures, suspension of review of applications or other submissions, rejection or delay in approval of applications, recall or seizure of products, total or partial suspension of production and/or distribution, our inability to sell products, the return by customers of our products, injunctions, and/or criminal prosecution. Under certain circumstances, a

regulator may also have the authority to revoke or vary previously granted drug approvals.

The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information about any of our marketed or investigational products, those authorities may require labeling changes, establishment of a risk evaluation and mitigation strategy or similar strategy, restrictions on a product's indicated uses or marketing, or post-approval studies or post-market surveillance. In addition, we are subject to regulations in various jurisdictions, including the Federal Drug Supply Chain Security Act in the U.S., the Falsified Medicines Directive in the EU and several other such regulations in other countries that require us to develop electronic systems to serialize, track, trace and authenticate units of our products through the supply chain

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and distribution system. Compliance with these regulations may result in increased expenses for us or impose greater administrative burdens on our organization, and failure to meet these requirements could result in fines or other penalties.

The FDA and comparable regulatory authorities also regulate the facilities and operational procedures that we use to manufacture our products. We must register our facilities with the FDA and similar regulators in other countries. Products must be manufactured in our facilities in accordance with cGMP or similar standards in each territory in which we manufacture. Compliance with such regulations and with our own quality standards requires substantial expenditures of time, money, and effort in multiple areas, including training of personnel, record-keeping, production, and quality control and quality assurance. The FDA and other regulatory authorities, including foreign authorities, periodically inspect our manufacturing facilities for compliance with cGMP or similar standards in the applicable territory. Regulatory approval to manufacture a drug is granted on a site-specific basis. Failure to comply with cGMP and other regulatory standards at one of our or our partners' or suppliers' manufacturing facilities could result in an adverse action brought by the FDA or other regulatory authorities, which could result in a receipt of an untitled or warning letter, fines, penalties, disgorgement, unanticipated compliance expenditures, rejection or delay in approval of applications, suspension of review of applications or other submissions, suspension of ongoing clinical trials, recall or seizure of products, total or partial suspension of production and/or distribution, our inability to sell products, the return by customers of our products, orders to suspend, vary, or withdraw marketing authorizations, injunctions, consent decrees, requirements to modify promotional materials or issue corrective information to healthcare practitioners, refusal to permit import or export, criminal prosecution and/or other adverse actions.

If any regulatory body were to delay, withhold, or withdraw approval of an application; require a recall or other adverse product action; require one of our manufacturing facilities to cease or limit production; or suspend, vary, or withdraw related marketing authorization, our business could be adversely affected. Delay and cost in obtaining FDA or other regulatory approval to manufacture at a different facility also could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

Although we have established internal quality and regulatory compliance programs and policies, there is no guarantee that these programs and policies, as currently designed, will meet regulatory agency standards in the future or will prevent instances of non-compliance with applicable laws and regulations. Additionally, despite efforts at compliance, from time to time we or our partners receive notices of manufacturing and quality-related observations following inspections by regulatory authorities around the world, as well as official agency correspondence regarding compliance. For example, on November 9, 2018, the FDA issued a warning letter with respect to our manufacturing plant in Morgantown, West Virginia. This action resulted from previously disclosed observations of the plant made by FDA in April 2018. We have implemented comprehensive restructuring and remediation activities at our Morgantown plant, and the issues raised in the warning letter are being addressed within the context of these activities. However, we or our partners may receive similar observations and correspondence in the future. If we are unable to resolve these observations and address regulator's concerns in a timely fashion, our business, financial condition, results of operations, cash flows, and/or ordinary share price could be materially affected.

We utilize controlled substances in certain of our current products and products in development, and therefore must meet the requirements of the Controlled Substances Act of 1970 and the related regulations administered by the Drug Enforcement Agency ("DEA") in the U.S., as well as those of similar laws in other countries where we operate. These laws relate to the manufacture, shipment, storage, sale, and use of controlled substances. The DEA and other regulatory agencies limit the availability of the controlled substances used in certain of our current products and products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. We must annually apply to the DEA and similar regulatory agencies for procurement quotas in order to obtain these substances. Any delay or refusal by the DEA or such similar agencies in establishing our procurement quota for controlled substances could delay or stop our clinical trials or product launches, or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

The use of legal, regulatory, and legislative strategies by both brand and generic competitors, including but not limited to “authorized generics” and regulatory petitions, as well as the potential impact of proposed and newly enacted legislation, may increase costs associated with the introduction or marketing of our generic products, could delay or prevent such introduction, and could significantly reduce our revenue and profit.

Our competitors, both branded and generic, often pursue strategies to prevent or delay generic alternatives to branded products. These strategies include, but are not limited to:

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entering into agreements whereby other generic companies will begin to market an authorized generic, which is the approved brand-name drug without the brand-name on its label, at the same time or after generic competition initially enters the market;

launching their own authorized generic product prior to or at the same time or after generic competition initially enters the market;

pricing a branded product at a discount equivalent to generic pricing, as was the case for Copaxone after the launch of our generic glatiramer acetate products;

filing petitions with the FDA or other regulatory bodies seeking to prevent or delay approvals, including timing the filings so as to thwart generic competition by causing delays of our product approvals;

contracting strategies among pharmaceutical manufacturers and PBMs that could decrease generic utilization and negatively impact our product launches;

seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence or to meet other requirements for approval, and/or to prevent regulatory agency review of applications;

initiating legislative or other efforts to limit the substitution of generic versions of brand pharmaceuticals;

filing suits for patent infringement and other claims that may delay or prevent regulatory approval, manufacture, and/or sale of generic products;

introducing “next-generation” products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the generic or the reference product for which we seek regulatory approval;

persuading regulatory bodies to withdraw the approval of brand-name drugs for which the patents are about to expire and converting the market to another product of the brand company on which longer patent protection exists;

obtaining extensions of market exclusivity by conducting clinical trials of brand drugs in pediatric populations or by other methods; and

seeking to obtain new patents on drugs for which patent protection is about to expire.

In the U.S., some companies have lobbied Congress for amendments to the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) that would give them additional advantages over generic competitors. For example, although the term of a company’s drug patent can be extended to reflect a portion of the time a new drug application (“NDA”, which is filed in the U.S. with the FDA when approval is sought to market a newly developed branded product and, in certain instances, for a new dosage form, a new delivery system or a new indication for a previously approved drug) is under regulatory review, some companies have proposed extending the patent term by a full year for each year spent in clinical trials rather than the one-half year that is currently permitted. If proposals like these in the U.S., Europe, or in other countries where we or our partners and suppliers operate were to become effective, or if any other actions by our competitors and other third parties to prevent or delay activities necessary to the approval, manufacture, or distribution of our products are successful, our entry into the market and our ability to generate revenues associated with new products may be delayed, reduced, or eliminated, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

If we are unable to successfully introduce new products in a timely manner, our future revenue and profitability may be adversely affected.

Our future revenues and profitability will depend, in part, upon our ability to successfully and timely develop, license, or otherwise acquire and commercialize new products. Product development is inherently risky, especially for new drugs for which safety and efficacy have not been established and/or the market is not yet proven as well as for complex generic drugs and biosimilars. Likewise, product licensing involves inherent risks, including, among others, uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to whether the supply of product meets certain specifications or terms such as license scope or termination rights. The development and commercialization process, particularly with regard to new and complex drugs, also requires substantial time, effort and financial resources. We, or a partner, may not be successful in commercializing such products on a timely basis, or at all, which could adversely affect our business, financial condition, results of operations, cash flows, and/or ordinary share price.

Before any prescription drug product, including generic drug products, can be marketed, marketing authorization approval is required by the relevant regulatory authorities and/or national regulatory agencies (for example, the FDA in the U.S. and the EMA in the EU). The process of obtaining regulatory approval to manufacture and market new branded and generic pharmaceutical products is rigorous, time consuming, costly, and inherently unpredictable. In addition, these regulatory agencies may be delayed

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in reviewing and approving products as a result of lapsed or insufficient funding, insufficient staffing or other factors beyond our control. As a result of Brexit, the EU has decided to move the headquarters of the EMA from the U.K. to the Netherlands by March 2019, which raises the possibility that any existing and/or new regulatory approval applications in the EU, whether for existing or new drug products, could be delayed as a result. Any delay in regulatory approval could impact the commercial or financial success of a product.

Outside the U.S., the approval process may be more or less rigorous, depending on the country, and the time required for approval may be longer or shorter than that required in the U.S. Bioequivalence, clinical, or other studies conducted in one country may not be accepted in other countries, the requirements for approval may differ among countries, and the approval of a pharmaceutical product in one country does not necessarily mean that the product will be approved in another country. We, or a partner or supplier, may be unable to obtain requisite approvals on a timely basis, or at all, for new products that we may develop, license or otherwise acquire. Moreover, if we obtain regulatory approval for a drug, it may be limited, for example, with respect to the indicated uses and delivery methods for which the drug may be marketed, or may include warnings, precautions or contraindications in the labeling, which could restrict our potential market for the drug. A regulatory approval may also include post-approval study or risk management requirements that may substantially increase the resources required to market the drug. Also, for products pending approval, we may obtain raw materials or produce batches of inventory to be used in efficacy and bioequivalence testing, as well as in anticipation of the product's launch. In the event that regulatory approval is denied or delayed, we could be exposed to the risk of this inventory becoming obsolete.

The approval process for generic pharmaceutical products often results in the relevant regulatory agency granting final approval to a number of generic pharmaceutical products at the time a patent claim for a corresponding branded product or other market exclusivity expires. This often forces us to face immediate competition when we introduce a generic product into the market. Additionally, further generic approvals often continue to be granted for a given product subsequent to the initial launch of the generic product. These circumstances generally result in significantly lower prices, as well as reduced margins, for generic products compared to branded products. New generic market entrants generally cause continued price, margin, and sales erosion over the generic product life cycle.

In the U.S., the Hatch-Waxman Act provides for a period of 180 days of generic marketing exclusivity for a "first applicant," that is the first submitted Abbreviated New Drug Application ("ANDA", which is filed in the U.S. with the FDA when approval is sought to market a generic equivalent of a drug product previously approved under an NDA and listed in the FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, popularly known as the "Orange Book" or for a new dosage strength for a drug previously approved under an ANDA) containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with the ANDA's reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, which under certain circumstances may be shared with other ANDAs filed on the same day, the FDA cannot grant final approval to later-submitted ANDAs for the same generic equivalent. If an ANDA is awarded 180-day exclusivity, the applicant generally enjoys higher market share, net revenues, and gross margin for that generic product. However, our ability to obtain 180 days of generic marketing exclusivity may be dependent upon our ability to obtain FDA approval or tentative approval within an applicable time period of the FDA's acceptance of our ANDA. If we are unable to obtain approval or tentative approval within that time period, we may risk forfeiture of such marketing exclusivity. By contrast, if we are not a "first applicant" to challenge a listed patent for such a product, we may lose significant advantages to a competitor with 180-day exclusivity, even if we obtain FDA approval for our generic drug product. The same would be true in situations where we are required to share our exclusivity period with other ANDA sponsors with Paragraph IV certifications.

In the EU and other countries and regions, there is no exclusivity period for the first generic product. The European Commission or national regulatory agencies may grant marketing authorizations to any number of generics.

If we are unable to navigate our products through the approval process in a timely manner, there could be an adverse effect on our product introduction plans, business, financial condition, results of operations, cash flows, and/or ordinary share price.

We expend a significant amount of resources on R&D efforts that may not lead to successful product introductions.

Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology, including our biosimilars program and respiratory platform. We conduct R&D primarily to enable us to gain approval for, manufacture, and market pharmaceuticals in accordance with applicable laws and regulations. We also partner with third parties to develop products. Typically, research expenses related to the development of innovative or complex compounds and the filing of marketing authorization applications for innovative and complex compounds (such as NDAs and biosimilar applications in the U.S.) are significantly greater than those expenses associated with the development of and filing of marketing authorization applications for most generic products (such as ANDAs in the U.S. and abridged applications in Europe).

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As we and our partners continue to develop new and/or complex products, our research expenses will likely increase. Because of the inherent risk associated with R&D efforts in our industry, including the high cost and uncertainty of conducting clinical trials (where required) particularly with respect to new and/or complex drugs, our, or a partner's, R&D expenditures may not result in the successful introduction of new pharmaceutical products approved by the relevant regulatory bodies. Also, after we submit a marketing authorization application for a new compound or generic product, the relevant regulatory authority may change standards and/or request that we conduct additional studies or evaluations and, as a result, we may incur approval delays as well as R&D costs in excess of what we anticipated.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. We or our partners may experience delays in our ongoing or future clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned, or be completed on schedule, if at all.

Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons. If we experience delays in the completion of, or the termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Finally, we cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on R&D efforts and are not able, ultimately, to introduce successful new and/or complex products as a result of those efforts, there could be a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price. Even if our products in development receive regulatory approval, such products may not achieve expected levels of market acceptance.

Even if we are able to obtain regulatory approvals for our new products, the success of those products is dependent upon market acceptance. Levels of market acceptance for our products could be impacted by several factors, including but not limited to:

- the availability, perceived advantages, and relative safety and efficacy of alternative products from our competitors;
- the degree to which the approved labeling supports promotional initiatives for commercial success;
- the prices of our products relative to those of our competitors;
- the timing of our market entry;
- the effectiveness of our marketing, sales, and distribution strategy and operations; and
- other competitor actions, including legal actions.

Additionally, studies of the proper utilization, safety, and efficacy of pharmaceutical products are being conducted by the industry, government agencies, and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety, and efficacy of previously marketed as well as future products. In some cases, such studies have resulted, and may in the future result, in the discontinuation or variation of product marketing authorizations or requirements for risk management programs, such as a patient registry. Any of these events could adversely affect our profitability, business, financial condition, results of operations, cash flows, and/or ordinary share price.

The development, approval process, manufacture and commercialization of biosimilar products involve unique challenges and uncertainties, and our failure to successfully introduce biosimilar products could have a negative impact on our business and future operating results.

We and our partners and suppliers are actively working to develop and commercialize biosimilar products. Although the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") established a framework for the review and approval of biosimilar products and the FDA has begun to review and approve biosimilar product applications, there

continues to be significant uncertainty regarding the regulatory pathway in the U.S., with the FDA continuing to issue and revise guidance related to its

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interpretation and implementation of the BPCIA. There is also uncertainty regarding the pathway to obtain approval for biosimilar products in other countries as well as uncertainty regarding the commercial pathway to successfully market and sell such products.

Moreover, biosimilar products generally involve extensive patent clearances and often involve patent infringement litigation related to multiple patents, which could delay or prevent the commercial launch of a biosimilar product for many years. If we are unable to obtain FDA or other non-U.S. regulatory authority approval for our products, we will be unable to market them. In addition, the development and manufacture of biosimilars pose unique challenges related to the supply of the materials needed to manufacture biosimilars. Access to and the supply of necessary biological materials may be limited, and government regulations restrict access to and regulate the transport and use of such materials.

Even if our biosimilar products are approved for marketing, the products may not be commercially successful, may require more time than expected to achieve market acceptance, and may not generate profits in amounts that are sufficient to offset the amount invested to obtain such approvals. Market success of biosimilar products will depend on demonstrating to regulators, patients, physicians and payors (such as insurance companies) that such products are safe and effective yet offer a more competitive price or other benefit over existing therapies. In addition, manufacturers of biologic products may try to dissuade physicians from prescribing or accepting biosimilar products. We may not be able to generate future sales of biosimilar products in certain jurisdictions and may not realize the anticipated benefits of our investments in the development, manufacture and sale of such products. If our development efforts do not result in the development and timely approval of biosimilar products or if such products, once developed and approved, are not commercially successful, or upon the occurrence of any of the above risks, our business, financial condition, results of operations, cash flows, and/or ordinary share price could be materially adversely affected.

Our business is highly dependent upon market perceptions of us, our products, and the safety and quality of our products, and may be adversely impacted by negative publicity or findings.

Market perceptions of us are very important to our business, especially market perceptions of our company, products and the safety and quality of our products. If we, our partners and suppliers, or our products suffer from negative publicity, or if any of our products or similar products which other companies distribute are subject to market withdrawal or recall or are proven to be, or are claimed to be, ineffective or harmful to consumers, then this could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price. Also, because we are dependent on market perceptions, negative publicity associated with product quality, patient illness, or other adverse effects resulting from, or perceived to be resulting from, our products, or our partners' and suppliers' manufacturing facilities, could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

A significant portion of our revenues is derived from sales to a limited number of customers.

A significant portion of our revenues is derived from sales to a limited number of customers. If we were to experience a significant reduction in or loss of business with one or more such customers, or if one or more such customers were to experience difficulty in paying us on a timely basis, our business, financial condition, results of operations, cash flows, and/or ordinary share price could be materially adversely affected.

In addition, a significant amount of our sales are to a relatively small number of drug wholesalers and retail drug chains. These customers represent an essential part of the distribution chain of generic pharmaceutical products. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation. This consolidation has resulted in these groups gaining additional purchasing leverage and, consequently, increasing the product pricing pressures facing our business. We expect this trend of increased pricing pressures to continue.

Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions increases the negotiating power of these groups, enabling them to attempt to extract price discounts, rebates, and other restrictive pricing terms on our products. These factors could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

During the years ended December 31, 2018, 2017 and 2016, Mylan's consolidated net sales to its three largest customers were approximately: 8%, 10%, and 11%, respectively, to Cardinal Health, Inc.; 12%, 13%, and 16%, respectively, to McKesson Corporation; and 8%, 8%, and 14%, respectively, to AmerisourceBergen Corporation. The supply of API into Europe may be negatively affected by recent regulations promulgated by the EU. All API imported into the EU has needed to be certified as complying with the good manufacturing practice standards established by the EU laws and guidance, as stipulated by the International Conference for Harmonization. These regulations place the certification requirement on the regulatory bodies of the exporting countries. Accordingly, the national regulatory authorities

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of each exporting country must: (i) ensure that all manufacturing plants within their borders that export API into the EU comply with EU manufacturing standards and (ii) for each API exported, present a written document confirming that the exporting plant conforms to EU manufacturing standards. The imposition of this responsibility on the governments of the nations exporting an API may cause delays in delivery or shortages of an API necessary to manufacture our products, as certain governments may not be willing or able to comply with the regulation in a timely fashion, or at all. A shortage in API may prevent us from manufacturing, or cause us to have to cease manufacture of, certain products, or to incur costs and delays to qualify other suppliers to substitute for those API manufacturers unable to export. The occurrence of any of the above risks could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

We have a limited number of manufacturing facilities and certain third-party suppliers produce a substantial portion of our API and products, some of which require a highly exacting and complex manufacturing process.

A substantial portion of our capacity, as well as our current production, is attributable to a limited number of manufacturing facilities and certain third-party suppliers. A significant disruption at any one of such facilities within our internal or third-party supply chain, even on a short-term basis, whether due to the failure of a third-party supplier to fulfill the terms of their agreement with us, labor disruption, adverse quality or compliance observation, other regulatory action, infringement of brand or other third-party intellectual property rights, natural disaster, civil or political unrest, export or import restrictions, or other events could impair our ability to produce and ship products to the market on a timely basis and could, among other consequences, subject us to exposure to claims from customers. Any of these events could have a material adverse effect on our reputation, business, financial condition, results of operations, cash flows, and/or ordinary share price. If we or our third-party suppliers' face significant manufacturing issues, this could lead to shutdowns or product shortages, or to our being entirely unable to supply certain products to customers for an extended period of time. Such shortages or shutdowns have led and could continue to lead to significant losses of sales revenue, third-party litigation, or negative publicity. See also "The pharmaceutical industry is heavily regulated, and we face significant costs and uncertainties associated with our efforts to comply with applicable laws and regulations."

We purchase certain API and other materials and supplies that we use in our manufacturing operations, as well as certain finished products, from many different foreign and domestic suppliers. The price of API and other materials and supplies is subject to volatility, and in certain cases, we have listed only one supplier in our applications with regulatory agencies. There is no guarantee that we will always have timely, sufficient or affordable access to critical raw materials or finished product supplied by third parties, even when we have more than one supplier. An increase in the price, or an interruption in the supply, of a single-sourced or any other raw material, including the relevant API, or in the supply of finished product, could cause our business, financial condition, results of operations, cash flows, and/or ordinary share price to be materially adversely affected. Quality deficiencies in the products which our suppliers provide, or at their manufacturing facilities, could adversely impact our manufacturing and supply capabilities, cause supply interruptions, or lead to voluntary market withdrawals or product recalls.

In addition, the manufacture of some of our products is a highly exacting and complex process, due in part to strict regulatory requirements. Problems may arise during manufacturing at our or our third-party suppliers' facilities for a variety of reasons, including, among others, equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, natural disasters, power outages, labor unrest, and environmental factors. If problems arise during the production of a batch of product, that batch of product may have to be discarded. This could, among other things, lead to increased costs, lost revenue, damage to customer relations, time and expense spent investigating the cause, and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

If we or one of our suppliers experience any of the problems described above, such problems could have a material adverse effect on our reputation, business, financial condition, results of operations, cash flows, and/or ordinary share price.

Our future success is highly dependent on our continued ability to attract and retain key personnel.

It is important that we attract and retain qualified personnel in order to develop and commercialize new products, manage our business, and compete effectively. Competition for qualified personnel in the pharmaceutical industry is very intense. If we fail to attract, develop, incentivize and retain key scientific, technical, commercial, regulatory or management personnel, this could lead to loss of customers, business disruption, and a decline in revenues, adversely affect the progress of pipeline products, or otherwise adversely affect our operations. Additionally, while we work to ensure that we have effective plans in place for management succession, any anticipated or unanticipated management transition could create uncertainty, which could disrupt or result in changes to our strategy and have a negative impact on our business. While we have employment agreements with certain key employees in place, their employment for the duration of the agreement is not guaranteed. Current and prospective employees might also experience uncertainty about their future roles with us following the consummation and integration of recent acquisitions and potential future transactions, which might adversely affect our ability to retain key managers and other employees. If we are

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unsuccessful in retaining our key employees or enforcing certain post-employment contractual provisions such as confidentiality or non-competition provisions, it could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

We are in the process of enhancing and further developing our global ERP systems and associated business applications, which could result in business interruptions if we encounter difficulties.

We are enhancing and further developing our global ERP and other business critical IT infrastructure systems and associated applications to provide more operating efficiencies and effective management of our business and financial operations. Such changes to ERP systems and related software, and other IT infrastructure carry risks such as cost overruns, project delays and business interruptions and delays. If we experience a material business interruption as a result of our ERP enhancements, it could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

Compliance Risks

We are subject to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act, and similar worldwide anti-corruption laws, which impose restrictions on certain conduct and may carry substantial fines and penalties.

We are subject to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and similar anti-corruption laws in other jurisdictions. These laws generally prohibit companies and their intermediaries from engaging in bribery or making other prohibited payments to government officials for the purpose of obtaining or retaining business, and some have record keeping requirements. The failure to comply with these laws could result in substantial criminal and/or monetary penalties. We operate in jurisdictions that have experienced corruption, bribery, pay-offs and other similar practices from time-to-time and, in certain circumstances, such practices may be local custom. We have implemented internal control policies and procedures that mandate compliance with these anti-corruption laws. However, we cannot be certain that these policies and procedures will protect us against liability. There can be no assurance that our employees or other agents will not engage in such conduct for which we might be held responsible. If our employees or agents are found to have engaged in such practices, we could suffer severe criminal or civil penalties and other consequences that could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

Our competitors, including branded pharmaceutical companies, and/or other third parties, may allege that we or our suppliers are infringing upon their intellectual property, including in an “at risk launch” situation, which could result in substantial monetary damages, impact our ability to launch a product and/or our ability to continue marketing a product, and/or force us to expend substantial resources in resulting litigation, the outcome of which is uncertain.

Companies that produce branded pharmaceutical products and other patent holders routinely bring litigation against entities selling or seeking regulatory approval to manufacture and market generic forms of their branded products, as well as other entities involved in the manufacture, supply, and other aspects relating to API and finished pharmaceutical products. These companies and other patent holders may allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an applicant for a generic product as well as others who may be involved in some aspect of research, supply, production, distribution, testing, packaging or other processes. Litigation often involves significant expense and can delay or prevent introduction or sale of our generic products. If patents are held valid and infringed by our products in a particular jurisdiction, we and/or our supplier(s) or partner(s) may, unless we or the supplier(s) or partner(s) could obtain a license from the patent holder, need to cease manufacturing and other activities, including but not limited to selling in that jurisdiction. We may also need to pay damages, surrender or withdraw the product, or destroy existing stock in that jurisdiction.

There also may be situations, including, for example, the decision to launch our 40mg/mL glatiramer acetate and Fulphila products, where we use our business judgment and decide to market, and sell products, directly or through third parties, notwithstanding the fact that allegations of patent infringement(s) and other third-party rights have not been finally resolved by the courts (i.e., an “at-risk launch”). The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, a reasonable royalty on sales, damages measured by the profits lost by the patent holder, or by profits earned by the infringer. If there is a finding by a court of willful infringement, the definition of which is subjective, such damages may be increased by up

to three times. Moreover, because of the discount pricing typically involved with bioequivalent products, patented branded products generally realize a substantially higher profit margin than generic or biosimilar products. An adverse decision in a case such as this, or a judicial order preventing us or our suppliers and partners from manufacturing, marketing, selling, and/or other activities necessary to the manufacture and distribution of our products, could result in substantial penalties, and/or have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

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We rely on the effectiveness of our patents, confidentiality agreements and other measures to protect our intellectual property rights.

Our ability to commercialize any branded product successfully will largely depend upon our or any partner's or supplier's ability to obtain and maintain patents and trademarks of sufficient scope to lawfully prevent third parties from developing and/or marketing infringing products. In the absence of intellectual property or other protection, competitors may adversely affect our branded products business by independently developing and/or marketing substantially equivalent products. It is also possible that we could incur substantial costs if we are required to initiate litigation against others to protect or enforce our intellectual property rights.

We have filed and/or own patent filings covering the API or formulation of, methods of making, and/or methods of using, our branded products and branded product candidates. We may not be issued patents based on patent applications already filed or that we file in the future. Further, due to other factors that affect patentability, and if patents are issued, they may be insufficient in scope to cover or otherwise protect our branded products. Patents are national in scope and therefore the issuance of a patent in one country does not ensure the issuance of a patent in any other country. Furthermore, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions and has been and remains the subject of significant litigation. Legal standards relating to scope and validity of patent claims are evolving and may differ in various countries. Any patents we have obtained, or obtain in the future, may be challenged, invalidated or circumvented. Moreover, the U.S. Patent and Trademark Office or any other governmental agency may commence inter partes review or interference proceedings involving, or consider other challenges to, our patents or patent applications. In addition, branded products often have market viability based upon the goodwill of the product name, which typically benefits from trademark protection.

Our branded products may therefore also be subject to risks related to the loss of trademark or patent protection or to competition from generic or other branded products. Challenges can come from other businesses, individuals or governments, and governments could require compulsory licensing of this intellectual property. Any challenge to, or invalidation or circumvention of, our intellectual property (including patents or patent applications, copyrights and trademark protection) would be costly, would require significant time and attention of our management, and could cause a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

We also rely on trade secrets, unpatented proprietary know-how, trademarks, regulatory exclusivity and continuing technological innovation that we seek to protect, in part by confidentiality agreements with licensees, suppliers, employees and consultants. These measures may not provide adequate protection for our unpatented technology. If these agreements are breached, it is possible that we will not have adequate remedies. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors or we may not be able to maintain the confidentiality of information relating to such products. If we are unable to adequately protect our technology, trade secrets or proprietary know-how, or enforce our intellectual property rights, this could cause a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

Our reporting and payment obligations related to our participation in U.S. federal healthcare programs, including Medicare, Medicaid and the Department of Veterans Affairs (the "VA"), are complex and often involve subjective decisions that could change as a result of new business circumstances, new regulations or agency guidance, or advice of legal counsel. Any failure to comply with those obligations could subject us to investigation, penalties, and sanctions.

U.S. federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal healthcare programs, including Medicare, Medicaid and the VA, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic

consequences.

Pharmaceutical manufacturers that participate in the Medicaid Drug Rebate Program, such as Mylan, are required to report certain pricing data to the Centers for Medicare & Medicaid Services (“CMS”), the federal agency that administers the Medicare and Medicaid programs. This data includes the Average Manufacturer Price (“AMP”) for each of the manufacturer’s covered outpatient drugs. CMS calculates a type of U.S. federal ceiling on reimbursement rates to pharmacies for multiple source drugs under the Medicaid program, known as the federal upper limit (“FUL”). Since April 2016, CMS is required to use the weighted average AMP for pharmaceutically and therapeutically equivalent multiple source drugs to calculate FULs, instead of the other pricing data CMS previously used. Although weighted average AMP-based FULs do not reveal Mylan’s individual AMP, publishing a weighted average AMP available to customers and the public at large could negatively affect our commercial price negotiations.

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In addition, a number of state and federal government agencies are conducting investigations of manufacturers' reporting practices with respect to Average Wholesale Prices ("AWP"). The government has alleged that reporting of inflated AWP has led to excessive payments for prescription drugs, and we may be named as a defendant in actions relating to pharmaceutical pricing issues and whether allegedly improper actions by pharmaceutical manufacturers led to excessive payments by Medicare, Medicaid and/or the VA.

Any governmental agencies or authorities that have commenced, or may commence, an investigation of us relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties, and possible exclusion from federal healthcare programs, including Medicare, Medicaid and/or the VA. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments - and even in the absence of any such ambiguity - a governmental authority may take a position contrary to a position we have taken, and may impose or pursue civil and/or criminal sanctions. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. There can be no assurance that our submissions will not be found by CMS or the VA to be incomplete or incorrect. Any failure to comply with the above laws and regulations, and any such penalties or sanctions could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

We are involved in various legal proceedings and certain government inquiries and may experience unfavorable outcomes of such proceedings or inquiries.

We are or may be involved in various legal proceedings and certain government inquiries or investigations, including, but not limited to, patent infringement, product liability, antitrust matters, breach of contract, and claims involving Medicare, Medicaid and/or VA reimbursements, or laws relating to sales, marketing, and pricing practices, some of which are described in our periodic reports, that involve claims for, or the possibility of, fines and penalties involving substantial amounts of money or other relief, including but not limited to civil or criminal fines and penalties and exclusion from participation in various government healthcare-related programs. With respect to government antitrust enforcement and private plaintiff litigation of so-called "pay for delay" patent settlements, large verdicts, settlements or government fines are possible, especially in the U.S. and EU. If any of these legal proceedings or inquiries were to result in an adverse outcome, the impact could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price. Refer to Note 19 Litigation included in Item 8 in this Annual Report on Form 10-K for further discussion of litigation matters.

Emerging developments in the U.S. legal landscape relative to the liability of generic pharmaceutical manufacturers for certain product liabilities claims could increase our exposure litigation costs and damages. Although we maintain a combination of self-insurance and commercial insurance, no reasonable amount of insurance can fully protect against all risks because of the potential liability inherent in the business of producing pharmaceuticals for human consumption. To the extent that a loss occurs, depending on the nature of the loss and the level of insurance coverage maintained, it could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

In addition, in limited circumstances, entities that we have acquired are party to litigation in matters under which we are, or may be, entitled to indemnification by the previous owners. Even in the case of indemnification, there are risks inherent in such indemnities and, accordingly, there can be no assurance that we will receive the full benefits of such indemnification, or that we will not experience an adverse result in a matter that is not indemnified, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

If we fail to comply with our corporate integrity agreement, we could be subject to substantial penalties and exclusion from participation in federal healthcare programs.

In August 2017, Mylan Inc. and Mylan Specialty L.P. entered into a Corporate Integrity Agreement (the "CIA") with the Office of Inspector General of the Department of Health and Human Services ("OIG-HHS"). The CIA has a five-year

term and requires, among other things, enhancements to our compliance program, fulfillment of reporting and monitoring obligations, management certifications and resolutions from Mylan Inc.'s board, as well as that an independent review organization annually review various matters relating to the Medicaid Drug Rebate Program, among other things. If we fail to comply with the CIA, the OIG-HHS may impose substantial monetary penalties or exclude us from federal healthcare programs, including Medicare, Medicaid or the VA, which could have a material adverse effect on our business, financial condition and results of operations.

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We are increasingly dependent on IT and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

Significant disruptions to our IT systems or breaches of information security could adversely affect our business. We are increasingly dependent on sophisticated IT systems and infrastructure to operate our business. We also have outsourced significant elements of our operations to third parties, some of which are outside the U.S., including significant elements of our IT infrastructure, and as a result we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our IT systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions. In addition, we and our vendors could be susceptible to third-party attacks on our IT systems. Such attacks are increasingly sophisticated and are made by groups and individuals with a wide range of motives and expertise, including state and quasi-state actors, criminal groups, “hackers” and others. Any security breach or other disruption to our or our vendors’ IT infrastructure could also interfere with or disrupt our business operations, including our manufacturing, distribution, R&D, sales and/or marketing activities.

In the ordinary course of business, we and our vendors collect, store and transmit large amounts of confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size and complexity of our and our vendors’ systems and the large amounts of confidential information that is present on them also makes them potentially vulnerable to security breaches from inadvertent or intentional actions by our employees, partners or vendors, or from attacks by malicious third parties. Maintaining the security, confidentiality and integrity of this confidential information (including trade secrets or other intellectual property, proprietary business information and personal information) is important to our competitive business position. However, such information can be difficult to protect. While we have taken steps to protect such information, and to ensure that the third-party vendors’ on which we rely have taken adequate steps to protect such information, there can be no assurance that our or our vendors’ efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential or material non-public information that could adversely affect our business operations or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information.

A breach of our or our vendors’ security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information, and/or adversely affect our business position. Further, any such interruption, security breach, or loss, misappropriation, and/or unauthorized access, use or disclosure of confidential information, including personal information regarding our patients and employees, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

We are subject to data privacy and security laws and regulations in many different jurisdictions and countries where we do business, and our or our vendors’ inability to comply could result in fines, penalties, reputational damage, and could impact the way we operate our business.

We are subject to laws and regulations governing the collection, use and transmission of personal information, including health information. As the legislative and regulatory landscape for data privacy and protection continues to evolve around the world, there has been an increasing focus on privacy and data protection issues that may affect our business, including the U.S.’s federal Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”), the EU’s General Data Protection Regulation (“GDPR”), and other laws and regulations described below. In the U.S., we may be subject to state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure and transmission of personal information. Each of these laws are subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we, or the third-party vendors’ on which we rely, fail to comply with applicable laws and regulations we could be subject to fines, penalties or sanctions, including

criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. In addition, EU member states and other jurisdictions have adopted data protection laws and regulations that impose significant compliance obligations. Implementation of the GDPR in EU member states in May 2018 introduced new data protection requirements in the EU and established a framework to govern data sharing and collection and related consumer privacy rights. The GDPR imposed significant compliance obligations, including the implementation of a number of processes and policies around our data collection and use. In addition, the GDPR includes significant penalties for non-compliance, with fines up to the higher

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of €20 million or 4% of total annual worldwide revenue. In general, GDPR, and other local privacy laws, could require adaptation of our technologies or practices to satisfy local privacy requirements and standards that may be more stringent than in the U.S.

Other countries in which we do business have, or are developing, laws governing the collection, use and transmission of personal information as well that may affect our business or require us to adapt our technologies or practices. These include Canada and several Latin American and Asian countries, which have constitutional protections for, or have adopted legislation protecting, individuals' personal information. Other countries, including Australia and Japan, have established specific legal requirements for cross-border transfers of personal information. Some countries, including India, are considering legislation implementing data protection requirements or requiring local storage and processing of data or similar requirements.

These and similar initiatives could increase the cost of developing, implementing or maintaining our IT systems, require us to allocate more resources to compliance initiatives or increase our costs. In addition, a failure by us, or our third-party vendors, to comply with applicable data privacy and security laws could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on the way we operate our business, our financial condition, results of operations, cash flows, and/or ordinary share price.

Increasing scrutiny and changing expectations from customers, regulators, investors, and other stakeholders with respect to our environmental, social and governance practices may impose additional costs on us or expose us to new or additional risks.

Companies are facing increasing scrutiny from customers, regulators, investors, and other stakeholders related to their environmental, social and governance practices. Investor advocacy groups, investment funds and influential investors are also increasingly focused on these practices, especially as they relate to the environment, health and safety, supply chain management, diversity and human rights. Failure to adapt to or comply with regulatory requirements or investor or stakeholder expectations and standards could negatively impact our reputation and the price of our ordinary shares. In addition, a number of our customers, including certain government purchasers, have adopted, or may adopt, procurement policies that include social and environmental requirements, or these customers may seek to include such provisions in their procurement contract terms and conditions. These social and environmental responsibility provisions and initiatives are subject to change, vary from jurisdiction to jurisdiction, and certain elements may be difficult and/or cost prohibitive for us to comply with given the inherent complexity of our external supply chain and the global scope of our operations. In certain circumstances, in order to meet the requirements or standards of our customers, we may be obligated to modify our sourcing practices or make other operational choices which may require additional investments and increase our costs or result in inefficiencies. Alternatively, we may be ineligible to participate in bids or tenders in certain markets, which may result in lost sales and revenues.

Any of the factors mentioned above, or the perception that we or our suppliers or contract manufacturers have not responded appropriately to the growing concern for such issues, regardless of whether we are legally required to do so, may damage our reputation and have a material adverse effect on our business, financial condition, results of operations cash flows and/or ordinary share price.

Finance Risks

We expect to be treated as a non-U.S. corporation for U.S. federal income tax purposes. Any changes to the tax laws or changes in other laws (including under applicable income tax treaties), regulations, rules, or interpretations thereof applicable to inverted companies and their affiliates, whether enacted before or after the EPD Business Acquisition, may materially adversely affect us.

Under current U.S. law, we believe that we should not be treated as a U.S. corporation for U.S. federal income tax purposes as a result of Mylan's acquisition of Mylan Inc. and the EPD Business (the "EPD Business Acquisition"). Changes to Section 7874 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), or to the U.S. Treasury Regulations promulgated thereunder, or interpretations thereof, or to other relevant tax laws (including applicable income tax treaties), could affect our status as a non-U.S. corporation for U.S. federal income tax purposes and the tax consequences to us and our affiliates. Any such changes could have prospective or retroactive application, and may apply even if enacted or promulgated now that the EPD Business Acquisition has closed.

If we were to be treated as a U.S. corporation for U.S. federal income tax purposes, or if the relevant tax laws (including applicable income tax treaties) change, we would be subject to significantly greater U.S. tax liability than currently contemplated as a non-U.S. corporation or if the relevant tax laws (including applicable income tax treaties) had not changed, which would have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

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The IRS may not agree that we should be treated as a non-U.S. corporation for U.S. federal income tax purposes. The IRS may not agree that we should be treated as a non-U.S. corporation for U.S. federal income tax purposes. Although we are not incorporated in the U.S. and expect to be treated as a non-U.S. corporation for U.S. federal income tax purposes, the IRS may assert that we should be treated as a U.S. corporation for U.S. federal income tax purposes. As disclosed in the tax footnote to our financial statements, we have received and responded to various IRS requests for information about the EPD Business Acquisition and our status as a non-U.S. corporation for U.S. federal income tax purposes. If we were to be treated as a U.S. corporation for U.S. federal income tax purposes, we would be subject to significantly greater U.S. tax liability, beginning February 27, 2015, than currently contemplated as a non-U.S. corporation, which would have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

If the intercompany terms of cross border arrangements that we have among our subsidiaries are determined to be inappropriate or ineffective, our tax liability may increase.

We have potential tax exposures resulting from the varying application of statutes, regulations, and interpretations which include exposures on intercompany terms of cross-border arrangements among our subsidiaries (including intercompany loans, sales, and services agreements) in relation to various aspects of our business, including manufacturing, marketing, sales, and delivery functions. Although we believe our cross-border arrangements among our subsidiaries are based upon internationally accepted standards and applicable law, tax authorities in various jurisdictions may disagree with and subsequently challenge the amount of profits taxed in their country, which may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

We may not be able to maintain competitive financial flexibility and our corporate tax rate and could adversely affect us and our shareholders.

We believe that our structure and operations give us the ability to achieve competitive financial flexibility and a competitive worldwide effective corporate tax rate. The material assumptions underlying our expected tax rates include the fact that we expect certain of our businesses will be operated outside of the U.S. and, as such, will be subject to a lower tax rate than operations in the U.S., which will result in a lower blended worldwide tax rate than we were previously able to achieve. We must also make assumptions regarding the effect of certain internal reorganization transactions, including various intercompany transactions. We cannot give any assurance as to what our effective tax rate will be, however, because of, among other reasons, uncertainty regarding the tax policies of the jurisdictions where we operate, potential changes of laws and interpretations thereof, and the potential for tax audits or challenges. Our actual effective tax rate may vary from our expectation and that variance may be material.

Additionally, the tax laws of the U.K., the Netherlands and other jurisdictions could change in the future, and such changes could cause a material change in our effective tax rate.

Any of the factors discussed above could materially increase our overall effective income tax rate and income tax expense and could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

Unanticipated changes in our tax provisions or exposure to additional income tax liabilities and changes in income tax laws and tax rulings may have a significant adverse impact on our effective tax rate and income tax expense.

We are subject to income taxes in many jurisdictions. Significant analysis and judgment are required in determining our worldwide provision for income taxes. In the ordinary course of business, there are many transactions and calculations where the ultimate tax determination is uncertain. The final determination of any tax audits or related litigation could be materially different from our income tax provisions and accruals.

Additionally, changes in the effective tax rate as a result of a change in the mix of earnings in countries with differing statutory tax rates, changes in our overall profitability, changes in the valuation of deferred tax assets and liabilities, the results of audits and the examination of previously filed tax returns by taxing authorities, and continuing assessments of our tax exposures could impact our tax liabilities and affect our income tax expense, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share

price.

We may become taxable in a jurisdiction other than the U.K. and this may increase the aggregate tax burden on us. Based on our current management structure and current tax laws of the U.S., the U.K., and the Netherlands, as well as applicable income tax treaties, and current interpretations thereof, the U.K. and the Netherlands competent authorities have

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determined that we are tax resident solely in the U.K. for the purposes of the Netherlands-U.K. tax treaty. We have received a binding ruling from the competent authorities in the U.K. and in the Netherlands confirming this treatment. We will therefore be tax resident solely in the U.K. so long as the facts and circumstances set forth in the relevant application letters sent to those authorities remain accurate. Even though we received a binding ruling, the applicable tax laws or interpretations thereof may change, or the assumptions on which such rulings were based may differ from the facts. As a consequence, we may become a tax resident of a jurisdiction other than the U.K. As a consequence, our overall effective income tax rate and income tax expense could materially increase, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price. We have a number of clean energy investments which are subject to various risks and uncertainties.

We have invested in clean energy operations capable of producing refined coal that we believe qualify for tax credits under Section 45 of the Code. Our ability to claim tax credits under Section 45 of the Code depends upon the operations in which we have invested satisfying certain ongoing conditions set forth in Section 45 of the Code. These include, among others, the emissions reduction, “qualifying technology”, and “placed-in-service” requirements of Section 45 of the Code, as well as the requirement that at least one of the operations’ owners qualifies as a “producer” of refined coal. While we have received some degree of confirmation from the IRS relating to our ability to claim these tax credits, the IRS could ultimately determine that the operations have not satisfied, or have not continued to satisfy, the conditions set forth in Section 45 of the Code.

In addition, Congress could modify or repeal Section 45 of the Code and remove the tax credits retroactively. In addition, Section 45 of the Code contains phase out provisions based upon the market price of coal, such that, if the price of coal rises to specified levels, we could lose some or all of the tax credits we expect to receive from these investments. Finally, when the price of natural gas or oil declines relative to that of coal, some utilities may choose to burn natural gas or oil instead of coal. Market demand for coal may also decline as a result of an economic slowdown and a corresponding decline in the use of electricity. If utilities burn less coal, eliminate coal in the production of electricity or are otherwise unable to operate for an extended period of time, the availability of the tax credits would also be reduced. During 2017 and 2018, as a result of a decline in current and expected future production levels at certain of our clean energy facilities, the Company impaired its investment balance and other assets and in 2018 we terminated certain of our clean energy investments. Additional impairments or terminations could occur in the future. The occurrence of any of the above risks could limit the value of our investment, result in increased costs, materially increase our tax burden or adversely affect our business, financial condition, results of operations, cash flows, and/or ordinary share price.

Currency fluctuations and changes in exchange rates could adversely affect our business, financial condition, results of operations, cash flows, and/or ordinary share price.

Although we report our financial results in U.S. Dollars, a significant portion of our revenues, indebtedness and other liabilities and our costs are denominated in non-U.S. currencies, including among others the Euro, Swedish Krona, Indian Rupee, Japanese Yen, Australian Dollar, Canadian Dollar, British Pound Sterling and Brazilian Real. Our results of operations and, in some cases, cash flows, have in the past been and may in the future be adversely affected by certain movements in currency exchange rates. Defaults or restructurings in other countries could have a similar adverse impact. From time to time, we may implement currency hedges intended to reduce our exposure to changes in foreign currency exchange rates. However, our hedging strategies may not be successful, and any of our unhedged foreign exchange exposures will continue to be subject to market fluctuations. The occurrence of any of the above risks could cause a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price

We have significant indebtedness, which could lead to adverse consequences or adversely affect our financial position and prevent us from fulfilling our obligations under such indebtedness, and any refinancing of this debt could be at significantly higher interest rates.

Our level of indebtedness could have important consequences, including but not limited to:

- increasing our vulnerability to general adverse economic and industry conditions;

requiring us to dedicate a substantial portion of our cash flow from operations to make debt service payments, thereby reducing the availability of cash flow to fund working capital, capital expenditures, acquisitions and investments and other general corporate purposes;

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limiting our flexibility in planning for, or reacting to, challenges and opportunities, and changes in our businesses and the markets in which we operate;

limiting our ability to obtain additional financing to fund our working capital, capital expenditures, acquisitions and debt service requirements and other financing needs;

increasing our vulnerability to increases in interest rates in general because a substantial portion of our indebtedness bears interest at floating rates; and

placing us at a competitive disadvantage to our competitors that have less debt.

Our ability to service our indebtedness will depend on our future operating performance and financial results, which will be subject, in part, to factors beyond our control, including interest rates and general economic, financial and business conditions. If we do not have sufficient cash flow to service our indebtedness, we may need to refinance all or part of our existing indebtedness, borrow more money or sell securities or assets, some or all of which may not be available to us at acceptable terms or at all. In addition, we may need to incur additional indebtedness in the future in the ordinary course of business. Although the terms of our credit agreements and our bond indentures allow us to incur additional debt, this is subject to certain limitations which may preclude us from incurring the amount of indebtedness we otherwise desire.

In addition, although Mylan expects to maintain an investment grade credit rating, a downgrade in the credit rating of Mylan or any indebtedness of Mylan or its subsidiaries could increase the cost of further borrowings or refinancings of such indebtedness, limit access to sources of financing in the future or lead to other adverse consequences.

In addition, if we incur additional debt, the risks described above could intensify. If global credit markets contract, future debt financing may not be available to us when required or may not be available on acceptable terms or at all, and as a result we may be unable to grow our business, take advantage of business opportunities, respond to competitive pressures or satisfy our obligations under our indebtedness. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price. Our credit facilities, senior unsecured notes, commercial paper program, other outstanding indebtedness and any additional indebtedness we incur in the future impose, or may impose, significant operating and financial restrictions on us. These restrictions limit our ability to, among other things, incur additional indebtedness, make investments, pay certain dividends, prepay other indebtedness, sell assets, incur certain liens, enter into agreements with our affiliates or restricting our subsidiaries' ability to pay dividends, merge or consolidate. In addition, our credit facilities require us to maintain specified financial ratios. A breach of any of these covenants or our inability to maintain the required financial ratios could result in a default under the related indebtedness. If a default occurs, the relevant lenders could elect to declare our indebtedness, together with accrued interest and other fees, to be immediately due and payable. These factors could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with U.S. GAAP. Any future changes in estimates, judgments and assumptions used or necessary revisions to prior estimates, judgments or assumptions or changes in accounting standards could lead to a restatement or revision to previously issued financial statements.

The Consolidated and Condensed Consolidated Financial Statements included in the periodic reports we file with the SEC are prepared in accordance with U.S. GAAP. The preparation of financial statements in accordance with U.S. GAAP involves making estimates, judgments and assumptions that affect reported amounts of assets, liabilities, revenues, expenses and income. Estimates, judgments and assumptions are inherently subject to change in the future and any necessary revisions to prior estimates, judgments or assumptions could lead to a restatement. Furthermore, although we have recorded reserves for litigation related contingencies based on estimates of probable future costs, such litigation related contingencies could result in substantial further costs. Also, any new or revised accounting standards may require adjustments to previously issued financial statements. Any such changes could result in corresponding changes to the amounts of liabilities, revenues, expenses and income.

On August 17, 2017, the Company announced that its subsidiaries, Mylan Inc. and Mylan Specialty L.P., signed an agreement with the U.S. Department of Justice ("DOJ") and two relators finalizing the \$465 million settlement, plus

interest, with the DOJ and other government agencies related to the classification of the EpiPen® Auto-Injector for purposes of the Medicaid Drug Rebate Program that Mylan had agreed to the terms of on October 7, 2016 (the “Medicaid Drug Rebate Program Settlement”). On April 25, 2017, Mylan received a comment letter from the staff of the SEC’s Division of Corporation Finance with respect to Mylan’s Annual Report on Form 10-K for the year ended December 31, 2016, requesting information regarding Mylan’s accounting treatment of the \$465 million Medicaid Drug Rebate Program Settlement with the DOJ, including with respect to the determinations

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that the settlement amount should be recorded as a charge against earnings in the third quarter of 2016 rather than against any earlier periods, and that the settlement amount should be classified as an expense rather than a reduction of revenue.

Any of the changes discussed above could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

We must maintain adequate internal controls and be able to provide an assertion as to the effectiveness of such controls on an annual basis.

Effective internal controls are necessary for us to provide reasonable assurance with respect to our financial reports. We spend a substantial amount of management and other employee time and resources to comply with laws, regulations and standards relating to corporate governance and public disclosure. In the U.S., such regulations include the Sarbanes-Oxley Act of 2002, SEC regulations and the NASDAQ listing standards. In particular, Section 404 of the Sarbanes-Oxley Act of 2002 requires management's annual review and evaluation of our internal control over financial reporting and attestation as to the effectiveness of these controls by our independent registered public accounting firm. If we fail to maintain the adequacy of our internal controls, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting. Additionally, internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud. Therefore, even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. In addition, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that the control may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. If we fail to maintain the adequacy of our internal controls, including any failure to implement required new or improved controls, this could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price. Our actual financial position and results of operations may differ materially from the unaudited pro forma financial information included in this annual report.

The unaudited pro forma financial information contained in this Annual Report on Form 10-K may not be indicative of what our financial position or results of operations would have been had the Meda transaction been completed on the dates indicated, nor are they indicative of the future operating results of Mylan N.V. The unaudited pro forma financial information has been derived from the historical consolidated financial statements of Mylan N.V., Mylan Inc., and Meda and reflects certain adjustments related to past operating performance and acquisition accounting adjustments, such as increased amortization expense based on the fair value of assets acquired, the impact of transaction costs, and the related income tax effects. The information upon which these adjustments have been made is subjective, and these types of adjustments are difficult to make with complete accuracy. Accordingly, the actual financial position and results of our operations following the Meda transaction may not be consistent with, or evident from, this unaudited pro forma financial information and other factors may affect our business, financial condition, results of operations, cash flows, and/or ordinary share price, including, among others, those described herein.

ITEM 1B. Unresolved Staff Comments

As previously disclosed, on April 25, 2017, Mylan received a comment letter from the staff of the SEC's Division of Corporation Finance with respect to Mylan's Annual Report on Form 10-K for the year ended December 31, 2016, requesting information regarding Mylan's accounting treatment of the \$465 million Medicaid Drug Rebate Program Settlement with the DOJ, including with respect to the determinations that the settlement amount should be recorded as a charge against earnings in the third quarter of 2016 rather than against any earlier periods, and that the settlement amount should be classified as an expense rather than a reduction of revenue. The Company responded to the comment letter in May 2017 and we will continue to respond to any additional correspondence from the SEC's Division of Corporation Finance. We believe that our accounting treatment for the aforementioned DOJ settlement is appropriate and consistent with all applicable accounting standards.

ITEM 2. Properties

For information regarding properties, refer to Item 1 "Business" in Part I of this Annual Report on Form 10-K.

ITEM 3. Legal Proceedings

For information regarding legal proceedings, refer to Note 19 Litigation included in Item 8 in this Annual Report on Form 10-K.

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PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our ordinary shares are traded on the NASDAQ Stock Market under the symbol "MYL". Our ordinary shares were also traded on the Tel Aviv Stock Exchange ("TASE"). On November 10, 2017, however, the Company announced that it was voluntarily delisting the Company's ordinary shares from trading on the TASE and the TASE delisting became effective on February 12, 2018.

As of January 23, 2019, there were approximately 128,000 holders of Mylan N.V. ordinary shares, including those held in street or nominee name.

The Company did not pay dividends in 2018 or 2017 and does not intend to pay dividends on its ordinary shares in the near future.

UNREGISTERED SALES OF DEBT SECURITIES

In the past three years, we have issued unregistered securities in connection with the following transactions:

In May 2018, Mylan Inc. issued €500 million aggregate principal amount of senior unsecured debt securities, comprised of 2.125% Euro Senior Notes due 2025. These notes were issued in a private offering exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), to persons outside of the U.S. pursuant to Regulation S under the Securities Act.

In April 2018, Mylan Inc. issued \$1.5 billion aggregate principal amount of senior unsecured debt securities, comprised of 4.550% Senior Notes due 2028 and 5.200% Senior Notes due 2048. These notes were issued in a private offering exempt from the registration requirements of the Securities Act, to qualified institutional buyers in accordance with Rule 144A under the Securities Act and to persons outside of the U.S. pursuant to Regulation S under the Securities Act. In November 2018, Mylan N.V. and Mylan Inc. filed a registration statement with the SEC with respect to an offer to exchange these notes for registered notes with the same aggregate principal amount and terms substantially identical in all material respects, which was declared effective on December 11, 2018. The exchange offer expired on January 9, 2019 and settled on January 10, 2019. 100% of each of the 4.550% Senior Notes due 2028 and the 5.200% Senior Notes due 2048 were exchanged.

In May 2017, Mylan N.V. issued €500 million aggregate principal amount of senior unsecured debt securities, comprised of floating rate Senior Notes due 2020. These notes were issued in a private offering exempt from the registration requirements of the Securities Act, to persons outside of the U.S. pursuant to Regulation S under the Securities Act.

In November 2016, Mylan N.V. issued €3.0 billion aggregate principal amount of senior unsecured debt securities, comprised of floating rate Senior Notes due 2018, 1.250% Senior Notes due 2020, 2.250% Senior Notes due 2024 and 3.125% Senior Notes due 2028. These notes were issued in a private offering exempt from the registration requirements of the Securities Act, to persons outside of the U.S. pursuant to Regulation S under the Securities Act.

In June 2016, Mylan N.V. issued \$6.5 billion aggregate principal amount of senior unsecured debt securities, comprised of 2.500% Senior Notes due 2019, 3.150% Senior Notes due 2021, 3.950% Senior Notes due 2026 and 5.250% Senior Notes due 2046. These notes were issued in a private offering exempt from the registration requirements of the Securities Act, to qualified institutional buyers in accordance with Rule 144A under the Securities Act and to persons outside of the U.S. pursuant to Regulation S under the Securities Act. In December 2016, Mylan N.V. and Mylan Inc. filed a registration statement with the SEC with respect to an offer to exchange these notes for registered notes with the same aggregate principal amount and terms substantially identical in all material respects, which was declared effective on January 3, 2017. The exchange offer expired on January 31, 2017 and settled on February 3, 2017.

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STOCK PERFORMANCE GRAPH

Set forth below is a performance graph comparing the cumulative total return (assuming reinvestment of dividends), in U.S. Dollars, for the calendar years ended December 31, 2014, 2015, 2016, 2017 and 2018 of \$100 invested on December 31, 2013 in the Company's ordinary shares, the Standard & Poor's 500 Index and the Dow Jones U.S. Pharmaceuticals Index.

| | December 31, 2013 | December 31, 2014 | December 31, 2015 | December 31, 2016 | December 31, 2017 | December 31, 2018 |
|-----------------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| Mylan N.V. ⁽¹⁾ | 100.00 | 129.88 | 124.59 | 87.90 | 97.49 | 63.13 |
| S&P 500 | 100.00 | 113.69 | 115.26 | 129.05 | 157.22 | 150.33 |
| Dow Jones U.S. Pharmaceuticals | 100.00 | 121.41 | 128.94 | 126.14 | 141.33 | 153.17 |

⁽¹⁾ Mylan Inc. prior to February 27, 2015.

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ITEM 6. Selected Financial Data

The selected consolidated financial data set forth below should be read in conjunction with “Management’s Discussion and Analysis of Results of Operations and Financial Condition” included in Item 7 and the Consolidated Financial Statements and related Notes to Consolidated Financial Statements included in Item 8 in this Annual Report on Form 10-K. The functional currency of the primary economic environment in which the operations of Mylan and its subsidiaries in the U.S. are conducted is the U.S. Dollar. The functional currency of non-U.S. subsidiaries is generally the local currency in the country in which each subsidiary operates.

Mylan N.V. is the successor to Mylan Inc., the information set forth below refers to Mylan Inc. for periods prior to February 27, 2015, and to Mylan N.V. on and after February 27, 2015.

| (In millions, except per share amounts) | Year Ended December 31, | | | | |
|--|-------------------------|------------|------------|------------|------------|
| | 2018 | 2017 | 2016 | 2015 | 2014 |
| Statements of Operations: | | | | | |
| Total revenues | \$11,433.9 | \$11,907.7 | \$11,076.9 | \$9,429.3 | \$7,719.6 |
| Cost of sales ⁽¹⁾ | 7,432.3 | 7,124.6 | 6,379.9 | 5,213.2 | 4,191.6 |
| Gross profit | 4,001.6 | 4,783.1 | 4,697.0 | 4,216.1 | 3,528.0 |
| Operating expenses: | | | | | |
| Research and development | 704.5 | 783.3 | 826.8 | 671.9 | 581.8 |
| Selling, general and administrative | 2,441.0 | 2,575.7 | 2,498.5 | 2,180.7 | 1,625.7 |
| Litigation settlements and other contingencies, net | (49.5) | (13.1) | 672.5 | (97.4) | (32.1) |
| Total operating expenses | 3,096.0 | 3,345.9 | 3,997.8 | 2,755.2 | 2,175.4 |
| Earnings from operations | 905.6 | 1,437.2 | 699.2 | 1,460.9 | 1,352.6 |
| Interest expense | 542.3 | 534.6 | 454.8 | 339.4 | 333.2 |
| Other expense, net | 64.9 | (0.4) | 122.7 | 206.1 | 44.9 |
| Earnings before income taxes | 298.4 | 903.0 | 121.7 | 915.4 | 974.5 |
| Income tax (benefit) provision | (54.1) | 207.0 | (358.3) | 67.7 | 41.4 |
| Net loss attributable to the noncontrolling interest | — | — | — | (0.1) | (3.7) |
| Net earnings attributable to Mylan N.V. ordinary shareholders | \$352.5 | \$696.0 | \$480.0 | \$847.6 | \$929.4 |
| Earnings per ordinary share attributable to Mylan N.V. ordinary shareholders | | | | | |
| Basic | \$0.69 | \$1.30 | \$0.94 | \$1.80 | \$2.49 |
| Diluted | \$0.68 | \$1.30 | \$0.92 | \$1.70 | \$2.34 |
| Weighted average ordinary shares outstanding: | | | | | |
| Basic | 514.5 | 534.5 | 513.0 | 472.2 | 373.7 |
| Diluted | 516.5 | 536.7 | 520.5 | 497.4 | 398.0 |
| Selected Balance Sheet data: | | | | | |
| Total assets ⁽²⁾⁽³⁾ | \$32,734.9 | \$35,806.3 | \$34,726.2 | \$22,267.7 | \$15,820.5 |
| Working capital ⁽²⁾⁽³⁾⁽⁴⁾ | 1,779.9 | 828.0 | 2,481.8 | 2,350.5 | 1,137.2 |
| Short-term borrowings | 1.9 | 46.5 | 46.4 | 1.3 | 330.7 |
| Long-term debt, including current portion of long-term debt ⁽²⁾ | 13,816.4 | 14,614.5 | 15,426.2 | 7,294.3 | 8,104.1 |
| Total equity | 12,167.1 | 13,307.6 | 11,117.6 | 9,765.8 | 3,276.0 |

Cost of sales includes the following amounts primarily related to the amortization of purchased intangibles from acquisitions: \$1.61 billion, \$1.44 billion, \$1.32 billion, \$854.2 million and \$375.9 million for the years ended December 31, 2018, 2017, 2016, 2015 and 2014, respectively. In addition, cost of sales included the following amounts

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related to impairment charges to intangible assets: \$224.0 million, \$80.8 million, \$68.3 million, \$31.3 million and \$27.7 million for the years ended December 31, 2018, 2017, 2016, 2015 and 2014, respectively.

Pursuant to the Company's adoption of Accounting Standards Update 2015-03, Interest - Imputation of Interest, as of December 31, 2015, deferred financing fees related to term debt have been retrospectively reclassified from
(2) other assets to long-term debt or the current portion of long-term debt, depending on the debt instrument, on the Consolidated Balance Sheets for all periods presented. The Company retrospectively reclassified approximately \$34.4 million for the year ended December 31, 2014.

Pursuant to the Company's adoption of Accounting Standards Update 2015-17, Balance Sheet Classification of Deferred Taxes, as of December 31, 2015, deferred tax assets and liabilities that had been previously classified as current have been retrospectively reclassified to noncurrent on the Consolidated Balance Sheets for all periods
(3) presented. The reclassification resulted in a decrease in current assets of approximately \$345.7 million for the year ended December 31, 2014. The reclassification resulted in a decrease in current liabilities of approximately \$0.2 million for the year ended December 31, 2014.

(4) Working capital is calculated as current assets minus current liabilities.

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ITEM 7. Management’s Discussion and Analysis of Financial Condition And Results of Operations

The following discussion and analysis addresses material changes in the financial condition and results of operations of Mylan N.V. and subsidiaries for the periods presented. Unless context requires otherwise, the “Company,” “Mylan,” “our” or “we” refer to Mylan N.V. and its subsidiaries.

This discussion and analysis should be read in conjunction with the Consolidated Financial Statements and the related Notes to Consolidated Financial Statements included in Item 8 in this Annual Report on Form 10-K, and our other SEC filings and public disclosures.

This Annual Report on Form 10-K contains “forward-looking statements.” These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include, without limitation, statements about Mylan’s future operations, anticipated business levels, future earnings, planned activities, anticipated growth, market opportunities, strategies, competition, and other expectations and targets for future periods. These may often be identified by the use of words such as “will,” “may,” “could,” “should,” “would,” “project,” “believe,” “anticipate,” “expect,” “plan,” “estimate,” “forecast,” “potential,” “pipeline,” “intend,” “continue,” “target,” “seek” or other similar words or comparable words.

Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to:

- actions and decisions of healthcare and pharmaceutical regulators;
- failure to achieve expected or targeted future financial and operating performance and results;
- uncertainties regarding future demand, pricing and reimbursement for our products;
- any regulatory, legal or other impediments to Mylan’s ability to bring new products to market, including, but not limited to, where Mylan uses its business judgment and decides to manufacture, market and/or sell products, directly or through third parties, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts (i.e., an “at-risk launch”);
- success of clinical trials and Mylan’s ability to execute on new product opportunities;
- any changes in or difficulties with our manufacturing facilities, including with respect to our remediation and restructuring activities, supply chain or inventory or our ability to meet anticipated demand;
- the scope, timing and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on our financial condition, results of operations and/or cash flows;
- the ability to meet expectations regarding the accounting and tax treatments of acquisitions, including Mylan’s acquisition of Mylan Inc. and EPD Business;
- changes in relevant tax and other laws, including but not limited to changes in the U.S. tax code and healthcare and pharmaceutical laws and regulations in the U.S. and abroad;
- any significant breach of data security or data privacy or disruptions to our IT systems;
- the ability to protect intellectual property and preserve intellectual property rights;
- the effect of any changes in customer and supplier relationships and customer purchasing patterns;
- the ability to attract and retain key personnel;
- the impact of competition;
- identifying, acquiring and integrating complementary or strategic acquisitions of other companies, products or assets being more difficult, time-consuming or costly than anticipated;
- the possibility that Mylan may be unable to achieve expected synergies and operating efficiencies in connection with strategic acquisitions, strategic initiatives or restructuring programs within the expected time-frames or at all;
- uncertainties and matters beyond the control of management, including but not limited to general political and economic conditions and global exchange rates; and
- inherent uncertainties involved in the estimates and judgments used in the preparation of financial statements, and the providing of estimates of financial measures, in accordance with U.S. GAAP and related standards or on an adjusted basis.

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For more detailed information on the risks and uncertainties associated with Mylan's business activities, see the risks described in Item 1A in this Annual Report on Form 10-K for the year ended December 31, 2018, and our other filings with the SEC.

You can access Mylan's filings with the SEC through the SEC website at www.sec.gov or through our website, and Mylan strongly encourages you to do so. Mylan routinely posts information that may be important to investors on our website at investor.mylan.com, and we use this website address as a means of disclosing material information to the public in a broad, non-exclusionary manner for purposes of the SEC's Regulation Fair Disclosure (Reg FD).

The contents of our website are not incorporated by reference in this Annual Report on Form 10-K and shall not be deemed "filed" under the Exchange Act, as amended.

Mylan undertakes no obligation to update any statements herein for revisions or changes after the filing date of this Annual Report on Form 10-K.

Company Overview

Mylan is a global pharmaceutical company committed to setting new standards in healthcare and providing 7 billion people access to high quality medicine. We offer a growing portfolio of more than 7,500 products, including prescription generic, branded generic, brand-name drugs and OTC remedies. We market our products in more than 165 countries and territories. Every member of our approximately 35,000-strong global workforce is dedicated to delivering better health for a better world.

Over the last several years, Mylan has transformed itself through a clear, consistent and differentiated strategy into a company that is built to last. Fueling that durability is a business model anchored in providing access, Mylan's core purpose.

Providing access requires that we satisfy the needs of an incredibly diverse global marketplace whose economic and political systems, approaches to delivering and paying for healthcare, languages and traditions, and customer and patient requirements vary by location and over time.

With these considerations in mind, we built and scaled our commercial, operational and scientific platforms to meet customers' evolving needs in ways that are globally consistent and locally sensitive. As a result, not only are we succeeding in expanding people's access to medicine, we are continually diversifying our business.

That diversification is what drives our durability. Durability allows us to withstand and overcome competitive pressures while continuing to innovate. It also allows us to generate consistent financial results, including reliable cash flows capable of supporting ongoing investments in long-term growth.

Certain Market and Industry Factors

The global pharmaceutical industry is a highly competitive and highly regulated industry. As a result, we face a number of industry-specific factors and challenges, which can significantly impact our results. The following discussion highlights some of these key factors and market conditions.

Generic products, particularly in the U.S., generally contribute most significantly to revenues and gross margins at the time of their launch, and even more so in periods of market exclusivity, or in periods of limited generic competition. As such, the timing of new product introductions can have a significant impact on the Company's financial results. The entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products. Additionally, pricing is often affected by factors outside of the Company's control.

For branded products, the majority of the product's commercial value is usually realized during the period in which the product has market exclusivity. In the U.S. and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there can often be very substantial and rapid declines in the branded product's sales. OTC products also participate in a competitive environment that includes both branded and private label products. In the OTC space, value is realized through innovation, access and consumer activation.

Certain markets in which we do business outside of the U.S. have undergone government-imposed price reductions, and further government-imposed price reductions are expected in the future. Such measures, along with the tender systems discussed below, are likely to have a negative impact on sales and gross profit in these markets. However, government

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initiatives in certain markets that appear to favor generic products could help to mitigate this unfavorable effect by increasing rates of generic substitution and penetration.

Additionally, a number of markets in which we operate outside of the U.S. have implemented, or may implement, tender systems for generic pharmaceuticals in an effort to lower prices. Generally speaking, tender systems can have an unfavorable impact on sales and profitability. Under such tender systems, manufacturers submit bids that establish prices for generic pharmaceutical products. Upon winning the tender, the winning company will receive priority placement for a period of time. The tender system often results in companies underbidding one another by proposing low pricing in order to win the tender. The loss of a tender by a third party to whom we supply API can also have a negative impact on our sales and profitability. Sales continue to be negatively affected by the impact of tender systems in certain countries.

Recent Developments

In the fourth quarter of 2016, the Company announced a restructuring program representing initial steps of a series of actions in certain locations that are anticipated to further streamline our operations globally. During the year ended December 31, 2018, the Company recorded pre-tax restructuring charges of \$240.2 million. Included within the restructuring charges during the year ended December 31, 2018 were \$144.5 million for non-cash asset impairment charges. The remaining restructuring charges during the year ended December 31, 2018 primarily related to severance and employee benefits. The restructuring program, other than the additional restructuring and remediation activities at the Morgantown, West Virginia plant described below, was substantially complete as of December 31, 2018. As a result of the overall actions taken under the restructuring program through December 31, 2018, management believes the potential annual savings will be between approximately \$400.0 million and \$475.0 million once fully realized, with the majority of these savings improving operating cash flow.

In April 2018, the FDA completed an inspection at Mylan's plant in Morgantown, West Virginia and made observations through a Form 483. The Company submitted a comprehensive response to the FDA and committed to a robust improvement plan. In addition, based upon the Company's recognition of the continued evolution of industry dynamics and regulatory expectations, during the second quarter of 2018, the Company commenced comprehensive restructuring and remediation activities, which are aimed at reducing complexity at the Morgantown plant and include the discontinuation and transfer to other manufacturing sites of a number of products, a reduction of the workforce and extensive process and plant remediation. In the fourth quarter of 2018, the Company received a warning letter related to the previously disclosed observations at the plant. The issues raised in the warning letter are being addressed within the context of the Company's comprehensive restructuring and remediation activities.

The Morgantown plant continues to supply products for the U.S. market while we execute on and assess the restructuring and remediation activities. However, these activities have led to a temporary disruption in supply of certain products. Importantly, the profitability of the transferred and discontinued products is not proportionate to the reduced volumes of those products as the Company expects that manufacturing costs related to transferred products will be reduced and many of the discontinued products have lower than average gross margins. In addition, as it relates to North America, no significant new product revenue is forecasted from the Morgantown plant in 2019, and we are forecasting that only five of our top 50 and only one out of the top 10 gross margin generating products will be manufactured in Morgantown in 2019.

For the year ended December 31, 2018, the Company has incurred expenses amounting to approximately \$258.3 million for incremental manufacturing variances, site remediation and restructuring charges related to the Morgantown plant. At this time, the total expenses related to the additional restructuring and remediation activities at the Morgantown plant cannot be reasonably estimated.

Mylan remains committed to maintaining the highest quality manufacturing standards at its facilities around the world and to continuous assessment and improvement in a time of evolving industry dynamics and regulatory expectations. In April 2018, the State of New York passed a budget which included the Opioid Stewardship Fund (the "Fund"). The Fund created an aggregate \$100 million annual assessment on all manufacturers and distributors licensed to sell or distribute opioids in New York. In December 2018 a federal judge struck down the law ruling that the law was an unconstitutional regulatory penalty. New York has appealed the ruling.

On January 30, 2019, the Company received FDA approval of Wixela™ Inhub™ (fluticasone propionate and salmeterol inhalation powder, USP), the first generic of GlaxoSmithKline's Advair Disku®. The commercial launch of the Wixela Inhub occurred in February 2019.

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Financial Summary

The table below is a summary of the Company's financial results for the year ended December 31, 2018 compared to the prior year period:

| (In millions, except per share amounts) | Year Ended December 31, | | Change | % Change |
|---|----------------------------|------------|-----------|-------------|
| | 2018 | 2017 | | |
| Total revenues | \$11,433.9 | \$11,907.7 | \$(473.8) | (4)% |
| Gross profit | 4,001.6 | 4,783.1 | (781.5) | (16)% |
| Earnings from operations | 905.6 | 1,437.2 | (531.6) | (37)% |
| Net earnings | 352.5 | 696.0 | (343.5) | (49)% |
| Diluted earnings per ordinary share | \$0.68 | \$1.30 | \$(0.62) | (47)% |

A detailed discussion of the Company's financial results can be found below in the section titled "Results of Operations." As part of this discussion, we also report sales performance using the non-GAAP financial measures of "constant currency" net sales and total revenues. These measures provides information on the change in net sales and total revenues assuming that foreign currency exchange rates had not changed between the prior and current period. The comparisons presented at constant currency rates reflect comparative local currency sales at the prior year's foreign exchange rates. We routinely evaluate our net sales and total revenues performance at constant currency so that sales results can be viewed without the impact of foreign currency exchange rates, thereby facilitating a period-to-period comparison of our operational activities, and believe that this presentation also provides useful information to investors for the same reason.

More information about non-GAAP measures used by the Company as part of this discussion, including adjusted cost of sales, adjusted gross margins, adjusted net earnings, and adjusted EPS (all of which are defined below), are discussed further in this Item 7 under Results of Operations and Results of Operations — Use of Non-GAAP Financial Measures.

Results of Operations
2018 Compared to 2017

| (In millions) | Year Ended December 31, | | | 2018 Currency Impact ⁽¹⁾ | 2018 Constant Currency Revenues | Constant Currency % Change ⁽²⁾ |
|--|-------------------------|------------|-------------|---|--|---|
| | 2018 | 2017 | % Change | | | |
| Net sales | | | | | | |
| North America | \$4,095.6 | \$4,969.6 | (18)% | \$(0.8) | \$4,094.8 | (18)% |
| Europe | 4,157.3 | 3,958.3 | 5% | (144.5) | 4,012.8 | 1% |
| Rest of World | 3,015.8 | 2,832.1 | 7% | 88.6 | 3,104.4 | 10% |
| Total net sales | 11,268.7 | 11,760.0 | (4)% | (56.7) | 11,212.0 | (5)% |
| Other revenues ⁽³⁾ | 165.2 | 147.7 | 12% | (2.0) | 163.2 | 10% |
| Consolidated total revenues ⁽⁴⁾ | \$11,433.9 | \$11,907.7 | (4)% | \$(58.7) | \$11,375.2 | (4)% |

⁽¹⁾ Currency impact is shown as unfavorable (favorable).

The constant currency percentage change is derived by translating net sales or revenues for the current period at

⁽²⁾ prior year comparative period exchange rates, and in doing so shows the percentage change from 2018 constant currency net sales or revenues to the corresponding amount in the prior year.

⁽³⁾ For the year ended December 31, 2018, other revenues in North America, Europe, and Rest of World were approximately \$112.4 million, \$27.1 million, and \$25.7 million, respectively.

(4) Amounts exclude intersegment revenue that eliminates on a consolidated basis.

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Total Revenues

For the year ended December 31, 2018, Mylan reported total revenues of \$11.43 billion, compared to \$11.91 billion for the comparable prior year period, representing a decrease of \$473.8 million, or 4%. Total revenues include both net sales and other revenues from third parties. Net sales for the year ended December 31, 2018 were \$11.27 billion, compared to \$11.76 billion for the comparable prior year period, representing a decrease of \$491.3 million, or 4%. Other revenues for the year ended December 31, 2018 were \$165.2 million, compared to \$147.7 million for the comparable prior year period, an increase of \$17.5 million. The increase in other revenues was primarily the result of consideration received from the licensing of intellectual property during the current year.

The decrease in net sales included a decrease in the North America segment of 18%. This decrease was partially offset by increases in the Europe segment of 5% and in the Rest of World segment of 7%. The overall decrease in net sales was primarily driven by a decrease in net sales from existing products. Net sales from existing products, partially offset by new product sales, decreased on a constant currency basis by approximately \$443.6 million primarily as a result of lower volumes, and to a lesser extent, pricing. Net sales were also negatively impacted by approximately \$104.5 million due to the adoption of new accounting standards. Mylan's net sales were favorably impacted by the effect of foreign currency translation, primarily reflecting changes in the U.S. Dollar as compared to the currencies of Mylan's subsidiaries in the EU, which was partially offset by the unfavorable impact from changes in the Indian Rupee and the Australian Dollar. The favorable impact of foreign currency translation on current year net sales was approximately \$56.7 million resulting in a decrease in constant currency net sales of approximately \$548.0 million, or 5%.

From time to time, a limited number of our products may represent a significant portion of our net sales, gross profit and net earnings. Generally, this is due to the timing of new product introductions and the amount, if any, of additional competition in the market. Our top ten products in terms of net sales, in the aggregate, represented approximately 20% and 21% for the years ended December 31, 2018 and 2017, respectively.

Net sales are derived from our three geographic reporting segments: North America, Europe and Rest of World. The graph below shows net sales by segment for the years ended December 31, 2018 and 2017 and the net change period over period.

North America Segment

Net sales from North America decreased by \$874.0 million or 18% during the year ended December 31, 2018 when compared to the prior year. This decrease was due primarily to lower volumes on existing products, including the EpiPen® Auto-Injector, partially offset by new product sales. The decline in volumes was primarily driven by the divestiture of certain contract manufacturing assets, the loss of exclusivity of certain products, actions associated with the restructuring and remediation activities at the Morgantown manufacturing plant and the timing of purchases of our products by customers. In addition, net sales were negatively impacted by \$149.7 million related to the implementation of new accounting standards. Pricing also declined when compared to the prior year. The impact of foreign currency translation on current period net sales was insignificant within North America.

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Europe Segment

Net sales from Europe increased by \$199.0 million or 5% for the year ended December 31, 2018 when compared to the prior year. This increase was primarily the result of the favorable impact of foreign currency translation, new product sales, and to a lesser extent, higher volumes of existing products. The favorable impact of foreign currency translation was approximately \$144.5 million, or 4%. Partially offsetting these items was lower pricing on existing products. Constant currency net sales increased by approximately \$54.5 million, or 1% when compared to the prior year.

Rest of World Segment

Net sales from Rest of World increased by \$183.7 million or 7% for the year ended December 31, 2018 when compared to the prior year. This increase was primarily the result of new product sales, and to a lesser extent, higher volumes of existing products including higher sales of key brands in China. The increase in net sales as a result of new products was primarily due to new product sales from the Company's ARV franchise combined with new product sales in Australia, Japan and China. The increase in net sales was partially offset by lower pricing on existing products and the unfavorable impact of foreign currency translation. Overall, net sales from Rest of World were unfavorably impacted by the effect of foreign currency translation of approximately \$88.6 million, or 3%. Constant currency net sales increased by approximately \$272.3 million, or 10%.

Cost of Sales and Gross Profit

Cost of sales increased from \$7.12 billion for the year ended December 31, 2017 to \$7.43 billion for the year ended December 31, 2018. Cost of sales was primarily impacted by purchase accounting related amortization of acquired intangible assets and other special items, which are described further in the section titled Use of Non-GAAP Financial Measures. Gross profit for the year ended December 31, 2018 was \$4.00 billion and gross margins were 35%. For the year ended December 31, 2017, gross profit was \$4.78 billion and gross margins were 40%. Gross margins were negatively impacted by approximately 270 basis points related to the incremental amortization from product acquisitions and intangible asset impairment charges. Gross margins were also negatively affected by approximately 220 basis points as a result of incremental manufacturing expenses, site remediation expenses and incremental restructuring charges incurred during the year principally as a result of the activities at the Company's Morgantown plant. In addition, gross margins were negatively impacted as a result of lower gross profit from the sales of existing products partially offset by gross margins on new product introductions primarily in North America. Adjusted gross margins were approximately 54% for the years ended December 31, 2018 and 2017. Adjusted gross margins were negatively impacted by lower gross profit from sales of existing products partially offset by gross margins on new product introductions primarily in North America.

A reconciliation between cost of sales, as reported under U.S. GAAP, and adjusted cost of sales and adjusted gross margin for the year ended December 31, 2018 compared to the year ended December 31, 2017 is as follows:

| (In millions) | Year Ended | | |
|--|--------------|------------|---|
| | December 31, | | |
| | 2018 | 2017 | |
| U.S. GAAP cost of sales | \$7,432.3 | \$7,124.6 | |
| Deduct: | | | |
| Purchase accounting amortization and other related items | (1,833.3) | (1,523.8) | |
| Acquisition related items | (2.9) | (2.8) | |
| Restructuring and related costs | (118.4) | (46.0) | |
| Other special items | (225.1) | (63.5) | |
| Adjusted cost of sales | \$5,252.6 | \$5,488.5 | |
| Adjusted gross profit ^(a) | \$6,181.3 | \$6,419.2 | |
| Adjusted gross margin ^(a) | 54 | % 54 | % |

(a) Adjusted gross profit is calculated as total revenues less adjusted cost of sales. Adjusted gross margin is calculated as adjusted gross profit divided by total revenues.

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Operating Expenses

Research & Development Expense

R&D expense for the year ended December 31, 2018 was \$704.5 million, compared to \$783.3 million for the prior year, a decrease of \$78.8 million. This decrease was primarily due to lower expenditures related to the Company's respiratory programs and lower expenses due to the reprioritization of global programs.

Selling, General & Administrative Expense

Selling, general and administrative ("SG&A") expense for the year ended December 31, 2018 was \$2.44 billion, compared to \$2.58 billion for the prior year, a decrease of \$134.7 million. The decrease is primarily due to the benefits of integration activities, lower restructuring charges, lower acquisition-related costs of approximately \$48.0 million, and reduced share-based compensation expense primarily due to the reversal of all of the cumulative expense totaling \$70.6 million related to the Company's One-Time Special Performance-Based Five-Year Realizable Value Incentive Program during the year ended December 31, 2018. These decreases were partially offset by an increase in bad debt expense of approximately \$26.5 million related to a special business interruption event for one customer, and \$20.0 million of compensation expense as an additional discretionary bonus for a certain group of employees. None of the employees eligible for this bonus are named executive officers.

Litigation Settlements and Other Contingencies, Net

During the year ended December 31, 2018, the Company recorded a net gain of \$49.5 million for litigation settlements and other contingencies, net, compared to \$13.1 million in the prior year.

The following table includes the losses/(gains) recognized in litigation settlements and other contingencies, net during the year ended December 31, 2018:

| (In millions) | Loss/(gain) |
|---|-------------|
| Respiratory delivery platform contingent consideration adjustment | \$ (44.0) |
| Jai Pharma Limited and other contingent consideration adjustments | 2.5 |
| Litigation settlements | (8.0) |
| Total litigation settlements and other contingencies, net | \$ (49.5) |

The following table includes the losses/(gains) recognized in litigation settlements and other contingencies, net during the year ended December 31, 2017:

| (In millions) | Loss/(gain) |
|---|-------------|
| Respiratory delivery platform contingent consideration adjustment | \$ (93.5) |
| Litigation settlements | 51.1 |
| Topicals Business contingent consideration adjustment | 23.5 |
| Jai Pharma Limited contingent consideration adjustment | 9.8 |
| Apicore contingent consideration adjustment | (4.0) |
| Total litigation settlements and other contingencies, net | \$ (13.1) |

Interest Expense

Interest expense for the year ended December 31, 2018 totaled \$542.3 million, compared to \$534.6 million for the year ended December 31, 2017, an increase of \$7.7 million. The increase is due to slightly higher average interest rates on debt issued in 2018 when compared to the debt instruments redeemed during 2018, which was partially offset by the impact of lower average long-term balances during the year ended December 31, 2018 compared to the prior year.

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Other Expense, Net

Other expense, net, was \$64.9 million for the year ended December 31, 2018, compared to net other income of \$0.4 million for the prior year. Other expense (income), net includes losses from equity affiliates, foreign exchange gains and losses, and interest and dividend income. Other expense (income), net was comprised of the following for the year ended December 31, 2018 and 2017, respectively:

| (In millions) | Year Ended December 31, | |
|---|----------------------------|---------|
| | 2018 | 2017 |
| Losses from equity affiliates, primarily clean energy investments | \$78.7 | \$58.0 |
| Foreign exchange gains, net | (20.0) | (48.1) |
| Other losses/(gains), net | 6.2 | (10.3) |
| Other expense (income), net | \$64.9 | (0.4) |

Income Tax (Benefit) Provision

For the year ended December 31, 2018, the Company recognized an income tax benefit of \$54.1 million, compared to an income tax provision of \$207.0 million for the comparable prior year. During the year ended December 31, 2018, a tax benefit of \$65.7 million was recorded as a result of the Company's settlement of certain federal and state audits. The tax provision for the year ended December 31, 2017 included a provisional net tax charge of \$128.6 million related to the December 2017 U.S. Tax Cuts and Jobs Act (the "Tax Act"). Also impacting the income tax benefit for the year ended December 31, 2018 versus the prior year was the changing mix of income earned in jurisdictions with differing tax rates, increases in valuation allowances on certain carryforward tax attributes, and the revaluation of deferred tax assets and liabilities in countries that changed their statutory corporate tax rate.

2017 Compared to 2016

| (In millions) | Year Ended December 31, | | | 2017 Currency Impact ⁽¹⁾ | 2017 Constant Currency Revenues ⁽²⁾ | Constant Currency % Change ⁽²⁾ |
|--|-------------------------|------------|-------------|---|---|--|
| | 2017 | 2016 | % Change | | | |
| Net sales | | | | | | |
| North America | \$4,969.6 | \$5,629.5 | (12)% | \$(6.8) | \$4,962.8 | (12)% |
| Europe | 3,958.3 | 2,953.8 | 34 % | (89.7) | 3,868.6 | 31 % |
| Rest of World | 2,832.1 | 2,383.8 | 19 % | (52.2) | 2,779.9 | 17 % |
| Total net sales | 11,760.0 | 10,967.1 | 7 % | (148.7) | 11,611.3 | 6 % |
| Other revenues ⁽³⁾ | 147.7 | 109.8 | 35 % | (0.8) | 146.9 | 34 % |
| Consolidated total revenues ⁽⁴⁾ | \$11,907.7 | \$11,076.9 | 8 % | \$(149.5) | \$11,758.2 | 6 % |

⁽¹⁾ Currency impact is shown as unfavorable (favorable).

The constant currency percentage change is derived by translating net sales or revenues for the current period at prior year comparative period exchange rates, and in doing so shows the percentage change from 2017 constant currency net sales or revenues to the corresponding amount in the prior year.

⁽³⁾ For the year ended December 31, 2017, other revenues in North America, Europe, and Rest of World were approximately \$86.5 million, \$36.5 million, and \$24.7 million, respectively.

⁽⁴⁾ Amounts exclude intersegment revenue that eliminates on a consolidated basis.

Total Revenues

For the year ended December 31, 2017, Mylan reported total revenues of \$11.91 billion compared to \$11.08 billion for the comparable prior year period, representing an increase of \$830.8 million, or 8%. Total revenues include both net sales and other revenues from third parties. Net sales for the year ended December 31, 2017 were \$11.76

billion, compared to \$10.97

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billion for the comparable prior year period, representing an increase of \$792.9 million, or 7%. Other revenues for the year ended December 31, 2017 were \$147.7 million, compared to \$109.8 million for the comparable prior year period, an increase of \$37.9 million. The increase in other revenues was principally the result of an incremental increase in royalty income from arrangements acquired in the acquisition of Meda.

The increase in total revenues included net sales growth in the Europe segment of 34% and in the Rest of World segment of 19%. Net sales declined in the North America segment by 12%. Contributing to the overall increase in total revenues were the incremental net sales from the acquisitions of Meda and the non-sterile, topicals-focused business (the “Topicals Business”) of Renaissance Acquisition Holdings, LLC of approximately \$1.41 billion. This increase was partially offset by a net decrease in net sales from existing products and lower new product introductions of approximately \$764.1 million. The decrease from existing products was due primarily to lower pricing and, to a lesser extent, lower volumes in 2017. Mylan’s total revenues were favorably impacted by the effect of foreign currency translation, primarily reflecting changes in the U.S. Dollar as compared to the currencies of Mylan’s subsidiaries in the European Union, India, and Australia, which was partially offset by the unfavorable impact from changes in the Japanese Yen and the Pound Sterling. The favorable impact of foreign currency translation on total revenues was approximately \$149.5 million resulting in an increase in constant currency total revenues of approximately \$681.3 million, or 6%.

From time to time, a limited number of our products may represent a significant portion of our net sales, gross profit and net earnings. Generally, this is due to the timing of new product introductions and the amount, if any, of additional competition in the market. Our top ten products in terms of net sales, in the aggregate, represented approximately 21% and 27% for the years ended December 31, 2017 and 2016, respectively.

Net sales are derived from our three geographic reporting segments: North America, Europe and Rest of World. The graph below shows net sales by segment for the years ended December 31, 2017 and 2016 and the net change period over period.

North America Segment

Net sales from North America decreased \$659.9 million, or 12% during the year ended December 31, 2017 when compared to 2016. Net sales of existing products decreased principally due to lower pricing and, to a lesser extent, lower volume. This was partially offset by the incremental net sales from the acquisitions of Meda and the Topicals Business, totaling approximately \$340.0 million. For the year ended December 31, 2017, as anticipated, the U.S. generics products experienced price erosion in the high-single-digits, which includes the impact of the loss of exclusivity of armodafinil, olmesartan and olmesartan HCTZ during 2017. Sales of the EpiPen®

Auto-Injector declined approximately \$655.4 million from 2016 as a result of the impact of the launch of the authorized generic, higher governmental rebates as a result of the Medicaid Drug Rebate Program Settlement, and increased competition. Excluding the negative impact of the lower sales of the EpiPen® Auto-Injector, overall third-party sales in North America were unchanged in 2017 compared with 2016. The impact of foreign currency translation on net sales was insignificant within North America.

Europe Segment

Net sales from Europe increased \$1.00 billion, or 34% during the year ended December 31, 2017 when compared to the prior year. This increase was primarily the result of net sales from the acquisition of Meda of approximately \$833.2 million during the year ended December 31, 2017. Net sales of existing products increased primarily as a result of sales of new products and favorable pricing and volume. The favorable impact of foreign currency translation on 2017 net sales was \$89.7 million, or 3% within Europe. Constant currency net sales increased by approximately \$914.8 million, or 31% when compared to the prior year.

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Rest of World Segment

Net sales from Rest of World increased by \$448.3 million or 19% during the year ended December 31, 2017 when compared to the prior year. This increase was primarily the result of incremental net sales from the acquisition of Meda totaling approximately \$229.2 million. In addition, net sales from existing products increased principally as a result of higher volume, particularly from our ARV franchise, and to a lesser extent Australia and the emerging markets. Throughout the segment, higher volumes and sales of new products more than offset lower pricing. The favorable impact of foreign currency translation was \$52.2 million, or 2%. Constant currency net sales increased by approximately \$396.1 million, or 17%.

Cost of Sales and Gross Profit

Cost of sales increased from \$6.38 billion for the year ended December 31, 2016 to \$7.12 billion for the year ended December 31, 2017. Cost of sales was primarily impacted by purchase accounting related amortization of acquired intangible assets, acquisition related costs, restructuring, and other special items, which are described further in the section titled Use of Non-GAAP Financial Measures. Gross profit for the year ended December 31, 2017 was \$4.78 billion and gross margins were 40%. For the year ended December 31, 2016, gross profit was \$4.70 billion and gross margins were 42%. Gross margins were negatively impacted in 2017 by incremental amortization expense as a result of the acquisitions of Meda and the Topicals Business by approximately 110 basis points, lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, by approximately 275 basis points, partially offset by the contributions from the acquired businesses. Adjusted gross margins were approximately 54% for the year ended December 31, 2017, compared to approximately 56% for the year ended December 31, 2016. Adjusted gross margins were negatively impacted in the current period as a result of lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, by approximately 200 basis points, partially offset by the contributions from the acquired businesses.

A reconciliation between cost of sales, as reported under U.S. GAAP, and adjusted cost of sales and adjusted gross margin for the year ended December 31, 2017 compared to the year ended December 31, 2016 is as follows:

| (In millions) | Year Ended December | | |
|--|---------------------|------------|---|
| | 31, 2017 | 2016 | |
| U.S. GAAP cost of sales | \$7,124.6 | \$6,379.9 | |
| Deduct: | | | |
| Purchase accounting amortization and other related items | (1,523.8) | (1,389.3) | |
| Acquisition related items | (2.8) | (2.3) | |
| Restructuring and related costs | (46.0) | (31.1) | |
| Other special items | (63.5) | (92.8) | |
| Adjusted cost of sales | \$5,488.5 | \$4,864.4 | |
| Adjusted gross profit ^(a) | \$6,419.2 | \$6,212.5 | |
| Adjusted gross margin ^(a) | 54 | % 56 | % |

^(a) Adjusted gross profit is calculated as total revenues less adjusted cost of sales. Adjusted gross margin is calculated as adjusted gross profit divided by total revenues.

Operating Expenses

Research & Development Expense

R&D expense for the year ended December 31, 2017 was \$783.3 million, compared to \$826.8 million for the prior year, a decrease of \$43.5 million. The decrease was due to lower spending when compared to the prior year as a result of the Company's reprioritization of global programs. Partially offsetting this decrease was the impact from incremental R&D expense related to the acquisitions of Meda and the Topicals Business of approximately \$45.4 million in the current year as well as an increase in restructuring costs included in R&D from \$7.7 million in 2016 to

\$8.4 million in 2017.

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Additionally, during the year ended December 31, 2017, the Company entered into a joint development and marketing agreement for a respiratory product resulting in approximately \$50.0 million in R&D expense. The Company also incurred R&D expense in 2017 of \$31.9 million related to the collaboration agreement with Momenta. In the prior year period, the Company made an upfront payment of \$45.0 million and incurred additional R&D expense of \$29.2 million, both related to the Company's collaboration agreement with Momenta which was entered into on January 8, 2016.

Selling, General & Administrative Expense

SG&A for the year ended December 31, 2017 was \$2.58 billion, compared to \$2.50 billion for the prior year, an increase of \$77.2 million. The increase is due primarily to additional incremental expense related to the acquisitions of Meda and the Topicals Business which increased SG&A by approximately \$213.1 million. Restructuring charges recorded in SG&A were \$133.6 million and \$113.1 million, respectively, for the years ended December 31, 2017 and December 31, 2016. Partially offsetting these increases were acquisition related costs which were \$110.8 million lower than the prior year as well as the year over year benefit of integration activities.

Litigation Settlements and Other Contingencies, Net

During the year ended December 31, 2017, the Company recorded net gains of \$13.1 million for litigation settlements and other contingencies, net, compared to a net charge of \$672.5 million in the prior year.

The following table includes the losses/(gains) recognized in litigation settlements and other contingencies, net during the year ended December 31, 2017:

| (In millions) | Loss/(gain) |
|---|-------------|
| Respiratory delivery platform contingent consideration adjustment | \$ (93.5) |
| Litigation settlements | 51.1 |
| Topicals Business contingent consideration adjustment | 23.5 |
| Jai Pharma Limited contingent consideration adjustment | 9.8 |
| Apicore contingent consideration adjustment | (4.0) |
| Total litigation settlements and other contingencies, net | \$ (13.1) |

The following table includes the losses/(gains) recognized in litigation settlements and other contingencies, net during the year ended December 31, 2016:

| (In millions) | Loss/(gain) |
|---|-------------|
| Medicaid Drug Rebate Program Settlement | \$ 465.0 |
| Modafinil antitrust litigation settlement | 165.0 |
| Strides Arcolab Limited ("Strides") Settlement | 90.0 |
| Respiratory delivery platform contingent consideration adjustment | (68.5) |
| Jai Pharma Limited contingent consideration adjustment | 12.6 |
| Other litigation settlements | 8.4 |
| Total litigation settlements and other contingencies, net | \$ 672.5 |

Interest Expense

Interest expense for the year ended December 31, 2017 totaled \$534.6 million, compared to \$454.8 million for the year ended December 31, 2016, an increase of \$79.8 million. The increase in 2017 is primarily due to the incremental impact of the issuance of the senior notes in June 2016 and, the Euro senior notes issued in November 2016 and May 2017. This increase was partially offset by the impact of the repayment of the 1.800% Senior Notes due 2016 and the 1.350% Senior Notes due 2016 in June and November of 2016, respectively, as well as the repayment of the Meda Term Loan and the partial repayment of the Mylan N.V. Term Loan.

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Other (Income) Expense, Net

Other (income) expense, net was \$0.4 million for the year ended December 31, 2017, compared to net expense of \$122.7 million for the prior year. Other (income) expense, net was comprised of the following for the years ended December 31, 2017 and 2016, respectively:

| (In millions) | Year Ended | |
|---|--------------|---------|
| | December 31, | |
| | 2017 | 2016 |
| Losses from equity affiliates, primarily clean energy investments | \$100.2 | \$112.8 |
| Clean energy investment adjustment, net gain | (42.2) | — |
| Foreign exchange gains, net | (48.1) | (0.5) |
| Interest income | (6.2) | (12.3) |
| Write off of deferred financing fees | 3.2 | 34.8 |
| Other gains, net | (7.3) | (12.1) |
| Other (income) expense, net | \$(0.4) | \$122.7 |

During 2017, as a result of a decline in current and expected future production levels at certain of the clean energy facilities the Company impaired its investment balance and other assets by approximately \$47.0 million and reduced the related long-term obligations for these investments by approximately \$89.0 million resulting in a net gain of \$42.0 million which was recognized as a component of the net loss of the equity method investments. In the prior year, other (income) expense, net included a foreign exchange net gain of \$0.5 million, which included \$128.6 million of losses related to the Company's SEK non-designated foreign currency contracts that were entered into to economically hedge the foreign currency exposure associated with the expected payment of the Swedish krona-denominated cash portion of the purchase price of the offer to the shareholders of Meda to acquire all of the outstanding shares of Meda. This loss was offset by foreign exchange gains of approximately \$30.5 million related to the mark-to-market impact for the November 2016 settlement of a portion of outstanding Meda shares and the remaining obligation on non-tendered Meda shares. In addition, the loss was offset by foreign exchange gains related to the mark-to-market on Euro denominated notes of approximately \$32.0 million and additional net gains as a result of the Company's foreign currency exchange risk management program.

Income Tax Provision (Benefit)

For the year ended December 31, 2017, the Company recognized an income tax provision of \$207.0 million, compared to an income tax benefit of \$358.3 million for the comparable prior year. On December 22, 2017, the Tax Act was signed into law making significant changes to the Code. Changes include, but are not limited to, a U.S. federal corporate income tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, and a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings of non-U.S. corporate subsidiaries of large U.S. shareholders as of December 31, 2017. The Company calculated its best estimate of the impact of the Tax Act in the 2017 income tax provision in accordance with our understanding of the Tax Act and available guidance and recorded a provisional net tax charge of \$128.6 million related to the Tax Act in the year ended December 31, 2017. In addition, the income tax provision for the year ended December 31, 2017 versus the prior year was impacted by the changing mix of income earned in jurisdictions with differing tax rates, statutory releases of certain tax uncertainties, increases in valuation allowances on certain carryforward tax attributes, the non-recurring nature of tax benefits obtained by the 2016 mergers of certain foreign subsidiaries, and the revaluation of deferred tax assets and liabilities in countries that changed their statutory corporate tax rate.

Use of Non-GAAP Financial Measures

Whenever the Company uses non-GAAP financial measures, we provide a reconciliation of the non-GAAP financial measures to their most directly comparable U.S. GAAP financial measure. Investors and other readers are encouraged to review the related U.S. GAAP financial measures and the reconciliation of non-GAAP measures to their most directly comparable U.S. GAAP measure and should consider non-GAAP measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with U.S. GAAP. Additionally, since these are not measures determined in accordance with U.S. GAAP, non-GAAP financial measures

have no standardized meaning across companies, or as prescribed by U.S. GAAP and, therefore, may not be comparable to the calculation of similar measures or measures with the same title used by other companies.

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Management uses these measures internally for forecasting, budgeting, measuring its operating performance, and incentive-based awards. Primarily due to acquisitions and other significant events which may impact comparability of our periodic operating results, we believe that an evaluation of our ongoing operations (and comparisons of our current operations with historical and future operations) would be difficult if the disclosure of our financial results was limited to financial measures prepared only in accordance with U.S. GAAP. We believe that non-GAAP financial measures are useful supplemental information for our investors and when considered together with our U.S. GAAP financial measures and the reconciliation to the most directly comparable U.S. GAAP financial measure, provide a more complete understanding of the factors and trends affecting our operations. The financial performance of the Company is measured by senior management, in part, using adjusted metrics as described below, along with other performance metrics. Management's annual incentive compensation is derived, in part, based on the adjusted EPS (as defined below) metric.

Adjusted Cost of Sales and Adjusted Gross Margin

We use the non-GAAP financial measure "adjusted cost of sales" and the corresponding non-GAAP financial measure "adjusted gross margin." The principal items excluded from adjusted cost of sales include restructuring, acquisition related and other special items and purchase accounting amortization and other related items, which are described in greater detail below.

Adjusted Net Earnings and Adjusted EPS

Adjusted net earnings is a non-GAAP financial measure and provides an alternative view of performance used by management. Management believes that, primarily due to acquisition activity and other significant events, an evaluation of the Company's ongoing operations (and comparisons of its current operations with historical and future operations) would be difficult if the disclosure of its financial results were limited to financial measures prepared only in accordance with U.S. GAAP. Management believes that adjusted net earnings and adjusted net earnings per diluted share ("adjusted EPS") are two of the most important internal financial metrics related to the ongoing operating performance of the Company, and are therefore useful to investors and that their understanding of our performance is enhanced by these adjusted measures. Actual internal and forecasted operating results and annual budgets used by management include adjusted net earnings and adjusted EPS.

The significant items excluded from adjusted cost of sales, adjusted net earnings and adjusted EPS include:

Purchase Accounting Amortization and Other Related Items

The ongoing impact of certain amounts recorded in connection with acquisitions of both businesses and assets is excluded from adjusted cost of sales, adjusted net earnings and adjusted EPS. These amounts include the amortization of intangible assets, inventory step-up and intangible asset impairment charges, including IPR&D. For the acquisition of businesses accounted for under the provisions of the Financial Accounting Standards Board Accounting Standards Codification ("ASC") 805, these purchase accounting impacts are excluded regardless of the financing method used for the acquisitions, including the use of cash, long-term debt, the issuance of ordinary shares, contingent consideration or any combination thereof.

Upfront and Milestone-Related R&D Expenses

These expenses and payments are excluded from adjusted net earnings and adjusted EPS because they generally occur at irregular intervals and are not indicative of the Company's ongoing operations. Also included in this adjustment are certain expenses related to the Company's collaboration agreement with Momenta including certain milestone related costs. Such costs include payments related to Mylan's future decisions, on a product by product basis, to continue with the development of such product in the collaboration after certain R&D work is performed. Related amounts are excluded from adjusted net earnings and adjusted EPS as Mylan considers such payments as additional upfront buy-in payments for the products.

Accretion of Contingent Consideration Liability and Other Fair Value Adjustments

The impact of changes to the fair value of contingent consideration and accretion expense are excluded from adjusted net earnings and adjusted EPS because they are not indicative of the Company's ongoing operations due to the variability of the amounts and the lack of predictability as to the occurrence and/or timing and management believes their exclusion is helpful to understanding the underlying, ongoing operational performance of the business.

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Restructuring, Acquisition Related and Other Special Items

Costs related to restructuring, acquisition and integration activities and other actions are excluded from adjusted cost of sales, adjusted net earnings and adjusted EPS, as applicable. These amounts include items such as:

Costs related to formal restructuring programs and actions, including costs associated with facilities to be closed or divested, employee separation costs, impairment charges, accelerated depreciation, incremental manufacturing variances, equipment relocation costs and other restructuring related costs;

Certain acquisition related remediation and integration and planning costs, as well as other costs associated with acquisitions such as advisory and legal fees and certain financing related costs, and other business transformation and/or optimization initiatives, which are not part of a formal restructuring program, including employee separation and post-employment costs;

The pre-tax loss of the Company's clean energy investments, whose activities qualify for income tax credits under the Code; only included in adjusted net earnings and adjusted EPS is the net tax effect of the entity's activities;

The pre-tax mark-to-market gains and losses of the Company's investments in marketable equity securities historically accounted for as available for sale securities; only included in adjusted net earnings and adjusted EPS are cumulative realized gains and losses;

Certain costs to further develop and optimize our global ERP systems, operations and supply chain; and

Other costs, incurred from time to time, related to certain special events or activities that lead to gains or losses, including, but not limited to, incremental manufacturing variances, asset write-downs, or liability adjustments.

The Company has undertaken restructurings and other optimization initiatives of differing types, scope and amount during the covered periods and, therefore, these charges should not be considered non-recurring; however, management excludes these amounts from adjusted net earnings and adjusted EPS because it believes it is helpful to understanding the underlying, ongoing operational performance of the business.

Litigation Settlements, Net

Charges and gains related to legal matters, such as those discussed in the Note 19 Litigation included in Item 8 in this Annual Report on Form 10-K are generally excluded from adjusted net earnings and adjusted EPS. Normal, ongoing defense costs of the Company made in the normal course of our business are not excluded.

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Reconciliation of Adjusted Net Earnings and Adjusted EPS

A reconciliation between net earnings and diluted earnings per share, as reported under U.S. GAAP, and adjusted net earnings and adjusted EPS for the periods shown follows:

| (In millions, except per share amounts) | Year Ended December 31, | | | | | |
|--|-------------------------|--------|-----------|--------|-----------|--------|
| | 2018 | | 2017 | | 2016 | |
| U.S. GAAP net earnings and U.S. GAAP diluted earnings per share | \$352.5 | \$0.68 | \$696.0 | \$1.30 | \$480.0 | \$0.92 |
| Purchase accounting related amortization (primarily included in cost of sales) ^(a) | 1,833.9 | | 1,529.7 | | 1,412.3 | |
| Litigation settlements and other contingencies, net | (49.5) | | (13.1) | | 672.5 | |
| Interest expense (primarily clean energy investment financing and accretion of contingent consideration) | 39.7 | | 47.3 | | 111.8 | |
| Clean energy investments pre-tax loss | 78.7 | | 47.1 | | 92.3 | |
| Acquisition related costs (primarily included in SG&A and cost of sales) ^(b) | 21.4 | | 72.8 | | 234.3 | |
| Restructuring related costs ^(c) | 240.2 | | 188.0 | | 161.6 | |
| Other special items included in: | | | | | | |
| Cost of sales ^(d) | 225.1 | | 63.5 | | 92.8 | |
| Research and development expense ^(e) | 118.2 | | 117.7 | | 121.3 | |
| Selling, general and administrative expense ^(f) | 43.7 | | 11.7 | | 30.4 | |
| Other expense, net ^(g) | 25.4 | | 13.8 | | (18.6) | |
| Tax effect of the above items and other income tax related items | (564.5) | | (329.7) | | (843.5) | |
| Adjusted net earnings and adjusted EPS | \$2,364.8 | \$4.58 | \$2,444.8 | \$4.56 | \$2,547.2 | \$4.89 |
| Weighted average diluted ordinary shares outstanding | 516.5 | | 536.7 | | 520.5 | |

Significant items for the year ended December 31, 2018 include the following:

- The increase in purchase accounting related amortization is primarily due to the increase in amortization expense as a result of the full impact of certain product rights acquisitions which occurred in 2017, the current year impact of the 2018 product rights acquisitions and impairment charges of \$224.0 million during the year ended December 31, 2018.
- ^(a) as a result of the full impact of certain product rights acquisitions which occurred in 2017, the current year impact of the 2018 product rights acquisitions and impairment charges of \$224.0 million during the year ended December 31, 2018.
- ^(b) Acquisition related costs incurred in 2017 and 2018 consist primarily of integration activities. For the year ended December 31, 2018, approximately \$118.4 million is included in cost of sales, approximately \$17.6 million is included in R&D and approximately \$104.5 million is included in SG&A. Refer to Note 17 Restructuring included in Item 8 in this Annual Report on Form 10-K for additional information.
- ^(c) Restructuring included in Item 8 in this Annual Report on Form 10-K for additional information. Increases relate primarily to expenses of \$155.8 million for certain incremental manufacturing variances and site remediation activities as a result of the activities at the Company's Morgantown plant and \$22.6 million for costs related to the recall of Valsartan products.
- ^(d) Increases relate primarily to expenses of \$155.8 million for certain incremental manufacturing variances and site remediation activities as a result of the activities at the Company's Morgantown plant and \$22.6 million for costs related to the recall of Valsartan products.
- ^(e) Adjustment primarily relates to non-refundable payments related to development collaboration agreements.
- ^(f) The increase for the year ended December 31, 2018 is primarily related to bad debt expense of approximately \$26.5 million primarily related to a special business interruption event for one customer. The increase for the year ended December 31, 2018 is primarily related to mark-to-market losses of investments in equity securities historically accounted for as available-for-sale securities and the cumulative realized gains on such investments.
- ^(g) equity securities historically accounted for as available-for-sale securities and the cumulative realized gains on such investments.

Liquidity and Capital Resources

Our primary source of liquidity is net cash provided by operating activities, which was \$2.34 billion for the year ended December 31, 2018. We believe that net cash provided by operating activities and available liquidity will continue to allow us to meet our needs for working capital, capital expenditures and interest and principal payments on debt obligations. Nevertheless, our ability to satisfy our working capital requirements and debt service obligations, or fund

planned capital expenditures, will substantially depend upon our future operating performance (which will be affected by prevailing economic conditions), and financial, business and other factors, some of which are beyond our control.

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Operating Activities

Net cash provided by operating activities increased by \$276.9 million to \$2.34 billion for the year ended December 31, 2018, as compared to net cash provided by operating activities of \$2.06 billion for the year ended December 31, 2017. Net cash provided by operating activities is derived from net earnings adjusted for non-cash operating items, gains and losses attributed to investing and financing activities and changes in operating assets and liabilities resulting from timing differences between the receipts and payments of cash, including changes in cash primarily reflecting the timing of cash collections from customers, payments to vendors and employees and tax payments in the ordinary course of business.

The net increase in net cash provided by operating activities was principally due to the following:

- a net increase in the amount of cash provided by changes in accounts receivable, including estimated sales allowances, of \$502.3 million, reflecting the timing of sales, cash collections and customer credits issued related to sales allowances;
- a net increase in the amount of cash provided by changes in trade accounts payable of \$205.9 million as a result of the timing of cash payments; and
- a net decrease in the amount of cash used through changes in other assets and liabilities of \$242.4 million, principally due to the timing of litigation and restructuring payments.

These items were partially offset by the following:

- a net increase of \$418.1 million in the amount of cash used through changes in inventory balances;
- an increase in the amount of cash used through changes in income taxes of \$39.1 million as a result of the level and timing of estimated tax payments made during the current period; and
- a net decrease in net earnings for the year ended December 31, 2018 of \$343.5 million when compared to the prior year period, principally as a result of a decrease in earnings from operations and a net increase in non-cash expenses of \$127.0 million. The increase in non-cash expenses was primarily due to increased depreciation and amortization of \$304.1 million, an increase in loss from equity method investments of \$20.7 million and decreased litigation settlements and other contingencies, net of \$8.5 million partially offset by a net increase in the deferred income tax benefit of \$152.9 million and a decrease in share-based compensation expense of \$78.0 million.

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Investing Activities

Net cash used in investing activities was \$1.21 billion for the year ended December 31, 2018, as compared to net cash used in investing activities of \$976.4 million for the year ended December 31, 2017, an increase of \$234.0 million.

In 2018, significant items in investing activities included the following:

- cash paid for acquisitions, net totaling approximately \$65.9 million related to the deferred non-contingent purchase price for the acquisition of Apicore;

- payments for product rights and other, net totaling approximately \$943.5 million, which included payments of approximately \$839 million related to commercialized product rights, primarily related to the worldwide rights to the TOBI Podhaler® and TOBI® solution, Betadine in certain European markets and other products in certain rest of world markets;

- proceeds from the sale of certain assets during the year totaling approximately \$29.3 million; and

- capital expenditures, primarily for equipment and facilities, totaling approximately \$252.1 million. While there can be no assurance that current expectations will be realized, capital expenditures for the 2019 calendar year are expected to be approximately \$250 million to \$400 million.

In 2017, significant items in investing activities included the following:

- cash paid for acquisitions, net totaling approximately \$167.0 million related to the acquisition of Apicore and the acquisition of the remaining non-tendered shares of Meda in the compulsory acquisition proceeding;

- payments for product rights and other, net totaling approximately \$620.3 million, which included a payment of \$50.0 million related to the acquisition of intellectual property rights for the Cold-EEZE® brand cold remedy line, payments of \$291.8 million related to acquisitions of additional intellectual property rights and marketing authorizations and a payment of \$256.7 million related to the acquisition of a portfolio of generic product rights in the U.S.;

- proceeds from the sale of certain assets and subsidiaries and assets during the year totaling approximately \$86.7 million; and

- capital expenditures, primarily for equipment and facilities, totaling approximately \$275.9 million.

Financing Activities

Net cash used in financing activities was \$1.09 billion for the year ended December 31, 2018, as compared to net cash used in financing activities of \$1.89 billion for the year ended December 31, 2017, a decrease of \$802.2 million.

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In 2018, significant items in financing activities included the following:

long-term debt proceeds of approximately \$2.58 billion primarily related to borrowings of approximately \$496.5 million under the 2016 Revolving Facility, proceeds from the April 2018 Senior Notes offering of approximately \$1.50 billion and proceeds from the May 2018 Euro Senior Notes offering of approximately €500 million (each as defined in Note 9 Debt included in Item 8 in this Annual Report on Form 10-K);

long-term debt payments of approximately \$3.17 billion consisting primarily of repayments of borrowings of approximately \$496.5 million under the 2016 Revolving Facility, redemptions of \$1.50 billion principal amount of senior notes in connection with the April 2018 Senior Notes offering, redemptions of \$600.0 million principal amount of senior notes in connection with the May 2018 Euro Senior Notes offering and repayment at maturity of €500.0 million principal amount of the Floating Rate Euro Notes due 2018;

net repayments of short-term borrowings of approximately \$44.4 million; and

the Company repurchased 9.8 million ordinary shares at a cost of approximately \$432.0 million and completed the \$1 billion share repurchase program that was previously approved by the Company's Board of Directors and announced on November 16, 2015 ("Share Repurchase Program").

In 2017, significant items in financing activities included the following:

long-term debt proceeds of approximately \$554.5 million related to the issuance of the €500 million May 2017 Floating Rate Euro Senior Notes (as defined below), \$320.0 million related to borrowings under the 2016 Revolving Facility and \$45.0 million borrowed under the Receivables Facility (as defined below);

long-term debt repayments consisting of a voluntarily prepayment of \$1.50 billion of the 2016 Term Facility (as defined in Note 9 Debt in Item 8 in this Annual Report on Form 10-K), the repayment of the Meda related debt during the year totaling approximately \$408.0 million and repayments of \$320.0 million of the borrowings under the 2016 Revolving Facility; and

the Company repurchased 12.4 million ordinary shares at a cost of approximately \$500.2 million as part of the Share Repurchase Program.

Capital Resources

Our cash and cash equivalents totaled \$388.1 million at December 31, 2018, and the majority of these funds are held by our non-U.S. subsidiaries. The Company anticipates having sufficient liquidity, including existing borrowing capacity under the 2018 Revolving Facility (as defined below), including the commercial paper program combined with cash to be generated from operations to fund foreseeable cash needs.

On December 22, 2017, the U.S. government enacted the Tax Act which makes broad and complex changes to the Code including, but not limited to, reducing the U.S. federal corporate income tax rate and requiring a one-time transition tax on certain unrepatriated earnings of non-U.S. corporate subsidiaries of large U.S. shareholders that may electively be paid over eight years. Our estimate of the transition tax obligation is \$99.1 million, which the Company has begun to pay, net of certain tax attributes and credit carryforwards, over eight years beginning in 2018.

As of December 31, 2018, our practice and intention was to reinvest the earnings in our non-U.S. subsidiaries outside of the U.S., and no U.S. deferred income taxes or foreign withholding taxes were recorded. The transition tax noted above resulted in the previously untaxed foreign earnings of U.S. subsidiaries being included in the federal and state taxable income.

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We analyze on an ongoing basis our global working capital requirements and the potential tax liabilities that would be incurred if the non-U.S. subsidiaries repatriate cash, which include potential local country withholding taxes and U.S. state taxation.

The Company has access to \$2.00 billion under the 2018 Revolving Facility. As of December 31, 2018, the Company had no amounts outstanding under the 2018 Revolving Facility (as defined below). Up to \$1.65 billion of the 2018 Revolving Facility may be used to support future borrowings under our commercial paper program.

In addition to the 2018 Revolving Facility, Mylan Pharmaceuticals Inc. (“MPI”), a wholly owned subsidiary of the Company, has a \$400 million receivables facility (the “Receivables Facility”), which expires on March 25, 2019. From time-to-time, the available amount of the Receivables Facility may be less than \$400 million based on accounts receivable concentration limits and other eligibility requirements. Under the terms of the Receivables Facility, MPI sells certain accounts receivable to Mylan Securitization LLC, a wholly owned special purpose entity which in turn sells a percentage of ownership interest in the receivables to financial institutions and commercial paper conduits sponsored by financial institutions. As of December 31, 2018, the Company had no short-term borrowings under the Receivables Facility.

At December 31, 2018, our long-term debt, including the current portion, totaled \$13.82 billion, as compared to \$14.61 billion at December 31, 2017. The decrease in long-term debt was due to redemptions of senior notes partially offset by issuances of senior notes in connection with the April 2018 Senior Notes offering and the May 2018 Euro Senior Notes offering and repayment at maturity of the Floating Rate Euro Notes due 2018 during the year ended December 31, 2018. The total long-term debt balance at December 31, 2018 was comprised primarily of \$12.66 billion of fixed rate senior notes and \$573.3 million of floating rate senior notes. In addition, at December 31, 2018, we had \$655.2 million of long-term debt classified as current and payable within the next twelve months, as compared to \$1.75 billion at December 31, 2017. The decrease to the current portion of long-term debt is due to the redemptions of the 2.600% Senior Notes due 2018, the 3.000% Senior Notes due 2018 and the repayment of the Floating Rate Euro Notes due 2018 partially offset by reclassification of the 2016 Term Facility which matures in November 2019 and the 2.500% Senior Notes due 2019 which mature in June 2019. The Company intends to utilize available liquidity to fund these repayments.

For additional information regarding our debt agreements, refer to Note 9 Debt included in Item 8 in this Annual Report on Form 10-K.

Long-term Debt Maturity

Mandatory minimum repayments remaining on the outstanding long-term debt at December 31, 2018, excluding the discounts and premiums, are as follows for each of the periods ending December 31:

The Company’s term credit facility dated as of November 22, 2016 (as amended, supplemented or otherwise modified from time to time, the “2016 Term Facility”), among the Company, certain affiliates and subsidiaries of the Company from time to time party thereto as guarantors, each lender from time to time party thereto and Goldman Sachs Bank USA, as administrative agent and the Company’s revolving credit facility dated as of July 27, 2018 (as amended, supplemented or otherwise modified from time to time, the “2018 Revolving Facility”), among Mylan Inc., as borrower, the Company, as a guarantor, certain lenders and issuing banks and Bank of America, N.A., as the administrative agent, contain customary affirmative covenants for facilities of this type, including among others, covenants pertaining to the delivery of financial statements, notices of default and certain material events, maintenance of corporate existence and rights, property, and insurance and compliance with laws, as well as customary negative covenants for facilities of this type, including limitations on the incurrence of subsidiary indebtedness, liens, mergers and certain other fundamental changes, investments and loans, acquisitions, transactions with affiliates, payments of dividends and other restricted payments and changes in our lines of business.

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The 2016 Term Facility and 2018 Revolving Facility contain a maximum consolidated leverage ratio financial covenant requiring maintenance of a maximum ratio of 3.75 to 1.00 for consolidated total indebtedness as of the end of any quarter to consolidated EBITDA for the trailing four quarters as defined in the related credit agreements ("leverage ratio").

The 2016 Term Facility was amended in November 2017 to allow a leverage ratio of 4.25 to 1.00 through the December 31, 2018 reporting period and a leverage ratio of 3.75 to 1.00 thereafter. The 2018 Revolving Facility similarly provides for a leverage ratio of 4.25 to 1.00 through the December 31, 2018 reporting period and a leverage ratio of 3.75 to 1.00 thereafter. On February 22, 2019, the Company, as a guarantor, and Mylan Inc., as borrower, entered into an amendment (the "Revolving Loan Amendment") to the 2018 Revolving Facility. In addition, on February 22, 2019, the Company entered into an amendment (the "Term Loan Amendment") to the 2016 Term Facility. The Revolving Loan Amendment and the Term Loan Amendment extended the leverage ratio covenant of 4.25 to 1.00 through the December 31, 2019 reporting period, with a leverage ratio of 3.75 to 1.00 thereafter. The Company is in compliance at December 31, 2018 and expects to remain in compliance for the next twelve months.

Other Commitments

The Company is involved in various disputes, governmental and/or regulatory inquiries, investigations and proceedings, tax proceedings and litigation matters, both in the U.S. and abroad, that arise from time to time, some of which could result in losses, including damages, fines and/or civil penalties, and/or criminal charges against the Company. These matters are often complex and have outcomes that are difficult to predict. The Company is also party to certain proceedings and litigation matters for which it may be entitled to indemnification under the respective sale and purchase agreements relating to the acquisitions of the former Merck Generics business, Agila Specialties Private Limited, the EPD Business, and certain other acquisitions. We have approximately \$54 million accrued for legal contingencies at December 31, 2018.

While the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position, the process of resolving these matters is inherently uncertain and may develop over a long period of time, and so it is not possible to predict the ultimate resolution of any such matter. It is possible that an unfavorable resolution of any of the ongoing matters or the inability or denial of Merck KGaA, Strides, Abbott Laboratories, or another indemnitor or insurer to pay an indemnified claim, could have a material adverse effect on the Company's business, financial condition, results of operations, cash flows and/or ordinary share price.

We are continuously evaluating the potential acquisition of products, as well as companies, as a strategic part of our future growth. Consequently, we may utilize current cash reserves or incur additional indebtedness to finance any such acquisitions, which could impact future liquidity. In addition, on an ongoing basis, we review our operations including the evaluation of potential divestitures of products and businesses as part of our future strategy. Any divestitures could impact future liquidity.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2018 and the effect that such obligations are expected to have on our liquidity and cash flows in future periods:

| (In millions) | Total | Less than One Year | One-Three Years | Three-Five Years | Thereafter |
|--|------------|--------------------|-----------------|------------------|------------|
| Long-term debt | \$13,913.0 | \$650.0 | \$4,183.0 | \$1,250.0 | \$7,830.0 |
| Scheduled interest payments ⁽¹⁾ | 5,237.5 | 466.0 | 844.6 | 689.9 | 3,237.0 |
| Operating leases ⁽²⁾ | 269.6 | 73.7 | 94.9 | 46.8 | 54.2 |
| Other Commitments ⁽³⁾ | 1,565.0 | 797.5 | 434.6 | 115.4 | 217.5 |
| | \$20,985.1 | \$1,987.2 | \$5,557.1 | \$2,102.1 | \$11,338.7 |

⁽¹⁾ Scheduled interest payments represent the estimated interest payments related to our outstanding borrowings under term loans, senior notes and other long-term debt. Variable debt interest payments are estimated using current

interest rates.

- (2) We lease certain properties under various operating lease arrangements that generally expire over the next five to seven years. These leases generally provide us with the option to renew the lease at the end of the lease term.

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Other commitments include funding commitments related to the Company's clean energy investments, agreements⁽³⁾ to purchase third-party manufactured products, open purchase orders, transition tax, estimated post-employment payments and capital leases at December 31, 2018.

Due to the uncertainty with respect to the timing of future payments, if any, the following contingent payments have not been included in the table above.

We are contractually obligated to make potential future development, regulatory and commercial milestone, royalty and/or profit sharing payments in conjunction with acquisitions we have entered into with third parties. The most significant of these relates to the potential future consideration related to the acquisition of the exclusive worldwide rights to develop, manufacture and commercialize a generic equivalent to GlaxoSmithKline's Advair® Diskus and Seretide® incorporating Pfizer's proprietary dry powder inhaler delivery platform (the "respiratory delivery platform"). These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when we may be required to pay such amounts. The amount of the contingent consideration liabilities was \$355.3 million at December 31, 2018. In addition, the Company expects to incur approximately \$15 million to \$20 million of non-cash accretion expense related to the increase in the net present value of the contingent consideration liabilities in 2019.

With respect to the timing of future cash flows associated with our unrecognized tax benefits at December 31, 2018, we are unable to make reasonably reliable estimates of the period of cash settlement with the respective taxing authority. As such, \$96.3 million of unrecognized tax benefits have been excluded from the contractual obligations table above.

We have entered into employment and other agreements with certain executives and other employees that provide for compensation and certain other benefits. These agreements provide for severance payments under certain circumstances. Certain commercial agreements require us to provide performance bonds and/or indemnification; while it is difficult to forecast the amount of payments, if any, to be made over the next few years, we do not believe the amount would be material to our results of operations, cash flows or financial condition.

Collaboration and Licensing Agreements

We periodically enter into collaboration and licensing agreements with other pharmaceutical companies for the development, manufacture, marketing and/or sale of pharmaceutical products. Our significant collaboration agreements are primarily focused on the development, manufacturing, supply and commercialization of multiple, high-value generic biologic compounds, insulin analog products and respiratory products, among other complex products. Under these agreements, we have future potential milestone payments and co-development expenses payable to third parties as part of our licensing, development and co-development programs. Payments under these agreements generally become due and are payable upon the satisfaction or achievement of certain developmental, regulatory or commercial milestones or as development expenses are incurred on defined projects. Milestone payment obligations are uncertain, including the prediction of timing and the occurrence of events triggering a future obligation and are not reflected as liabilities in the Consolidated Balance Sheets, except for milestone and royalty obligations reflected as acquisition related contingent consideration. Refer to Note 8 Financial Instruments and Risk Management included in Item 8 in this Annual Report on Form 10-K for further discussion of contingent consideration. Our potential maximum development milestones not accrued for at December 31, 2018 totaled approximately \$425 million. We estimate that the amounts that may be paid in the next twelve months to be approximately \$35 million. These agreements may also include potential sales-based milestones and call for us to pay a percentage of amounts earned from the sale of the product as a royalty or a profit share. The amounts disclosed do not include sales-based milestones or royalty obligations on future sales of product as the timing and amount of future sales levels and costs to produce products subject to these obligations is not reasonably estimable. These sales-based milestones or royalty obligations may be significant depending upon the level of commercial sales for each product.

The Company's significant collaboration and licensing agreements include agreements with Pfizer, Momenta, Theravance Biopharma, and Biocon. Refer to Note 18 Collaboration and Licensing Agreements included in Item 8 in this Annual Report on Form 10-K for additional information related to our collaborations.

Impact of Currency Fluctuations and Inflation

Because our results are reported in U.S. Dollars, changes in the rate of exchange between the U.S. Dollar and the local currencies in the markets in which we operate, mainly the Euro, Swedish Krona, Indian Rupee, Japanese Yen, Australian Dollar, Canadian Dollar, Pound Sterling and Brazilian Real affect our results as previously noted. We do not believe that inflation has had a material impact on our revenues or operations in any of the past three years.

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Application of Critical Accounting Policies

Our significant accounting policies are described in Note 2 Summary of Significant Accounting Policies included in Item 8 in this Annual Report on Form 10-K and are in accordance with U.S. GAAP.

Included within these policies are certain policies which contain critical accounting estimates and, therefore, have been deemed to be “critical accounting policies.” Critical accounting estimates are those which require management to make assumptions about matters that were uncertain at the time the estimate was made and for which the use of different estimates, which reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur from period to period could have a material impact on our financial condition or results of operations. We have identified the following to be our critical accounting policies: the determination of net revenue provisions, acquisitions, intangible assets, goodwill and contingent consideration, income taxes and the impact of existing legal matters.

Revenue Recognition

On January 1, 2018, the Company adopted ASC Topic 606 Revenue from Contracts with Customers (“ASC 606”) using the modified retrospective method applied to those contracts which were not completed as of the date of adoption. Results for reporting periods beginning on January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with ASC Topic 605 Revenue Recognition (“ASC 605”). Under ASC 605, the Company recognized net sales when title and risk of loss passed to its customers and when provisions for estimates, as described below, were reasonably determinable.

Under ASC 606, the Company recognizes net revenue for product sales when control of the promised goods or services is transferred to our customers in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. Revenues are recorded net of provisions for variable consideration, including discounts, rebates, governmental rebate programs, price adjustments, returns, chargebacks, promotional programs and other sales allowances. Accruals for these provisions are presented in the consolidated financial statements as reductions in determining net sales and as a contra asset in accounts receivable, net (if settled via credit) and other current liabilities (if paid in cash). The following briefly describes the nature of our provisions for variable consideration and how such provisions are estimated:

Chargebacks: the Company has agreements with certain indirect customers, such as independent pharmacies, retail pharmacy chains, managed care organizations, hospitals, nursing homes, governmental agencies and pharmacy benefit managers, which establish contract prices for certain products. The indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices.

Alternatively, certain wholesalers may enter into agreements with indirect customers that establish contract pricing for certain products, which the wholesalers provide. Under either arrangement, Mylan will provide credit to the wholesaler for any difference between the contracted price with the indirect party and the wholesaler’s invoice price. Such credits are called chargebacks. The provision for chargebacks is based on expected sell-through levels by our wholesaler customers to indirect customers, as well as estimated wholesaler inventory levels. We continually monitor our provision for chargebacks and evaluate our reserve and estimates as additional information becomes available. A change of 5% would have an effect on our reserve balance of approximately \$23.9 million.

Rebates, promotional programs and other sales allowances: this category includes rebate and other programs to assist in product sales. These programs generally provide that the customer receives credit directly related to the amount of purchases or credits upon the attainment of pre-established volumes. Also included in this category are prompt pay discounts, administrative fees and price adjustments to reflect decreases in the selling prices of products. A change of 5% would have an effect on our reserve balance of approximately \$60.1 million.

Returns: consistent with industry practice, Mylan maintains a return policy that allows customers to return a product, which varies country by country in accordance with local practices, generally within a specified period prior (six months) and subsequent (twelve months) to the expiration date. The Company’s estimate of the provision for returns is generally based upon historical experience with actual returns. A change of 5% would have an effect on our reserve balance of approximately \$22.0 million.

Governmental rebate programs: government reimbursement programs include Medicare, Medicaid, and State Pharmacy Assistance Programs established according to statute, regulations and policy. Manufacturers of pharmaceutical products that are covered by the Medicaid program are required to pay rebates to each state based on a statutory formula set forth in the Social Security Act. Medicare beneficiaries are eligible to obtain discounted prescription drug coverage from private sector providers. In addition, certain states have also implemented supplemental rebate programs that obligate manufacturers to pay rebates in excess of those required under federal law. Our estimate of these rebates is based on the historical trends of rebates paid as well as on changes in wholesaler

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inventory levels and increases or decreases in the level of sales. Also, this provision includes price reductions that are mandated by law outside of the U.S. A change of 5% would have an effect on our reserve balance of approximately \$11.1 million.

The following is a rollforward of the categories of variable consideration during 2018:

| (In millions) | Balance at December 31, 2017 | Current Provision Related to Sales Made in the Current Period | Checks/ Credits Issued to Third Parties | Effects of Foreign Exchange | Balance at December 31, 2018 |
|--|------------------------------------|--|---|-----------------------------------|------------------------------------|
| Chargebacks | \$ 574.3 | \$ 3,352.2 | \$(3,447.1) | \$ (1.2) | \$ 478.2 |
| Rebates, promotional programs and other sales allowances | 1,508.1 | 4,235.6 | (4,526.0) | (15.3) | 1,202.4 |
| Returns | 472.5 | 261.6 | (292.1) | (2.5) | 439.5 |
| Governmental rebate programs | 240.3 | 470.0 | (486.6) | (1.5) | 222.2 |
| Total | \$ 2,795.2 | \$ 8,319.4 | \$(8,751.8) | \$ (20.5) | \$ 2,342.3 |

Accruals for these provisions are presented in the Consolidated Financial Statements as reductions in determining net revenues and in accounts receivable and other current liabilities. Accounts receivable are presented net of allowances relating to these provisions, which were comprised of the following at December 31, 2018 and 2017, respectively:

| (In millions) | December 31, 2018 | December 31, 2017 |
|---------------------------|----------------------|----------------------|
| Accounts receivable | \$ 1,715.6 | \$ 1,977.2 |
| Other current liabilities | 626.7 | 818.0 |
| Total | \$ 2,342.3 | \$ 2,795.2 |

We have not made and do not anticipate making any significant changes to the methodologies that we use to measure provisions for variable consideration; however, the balances within these reserves can fluctuate significantly through the consistent application of our methodologies. Historically, we have not recorded in any current period any material amounts related to adjustments made to prior period reserves.

Acquisitions, Intangible Assets, Goodwill and Contingent Consideration

We account for acquired businesses using the acquisition method of accounting in accordance with the provisions of ASC 805, which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective estimated fair values. The cost to acquire businesses has been allocated to the underlying net assets of the acquired businesses based on estimates of their respective fair values. Amounts allocated to acquired IPR&D are capitalized at the date of an acquisition and, at that time, such IPR&D assets have indefinite lives. As products in development are approved for sale, amounts will generally be allocated to product rights and licenses and will be amortized over their estimated useful lives. Finite-lived intangible assets are amortized over the expected life of the asset. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

Purchases of developed products and licenses that are accounted for as an asset acquisition are capitalized as intangible assets and amortized over an estimated useful life. IPR&D assets acquired as part of an asset acquisition are expensed immediately if they have no alternative future uses.

The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact our results of operations. Fair values and useful lives are determined based on, among other factors, the expected future period of benefit of the asset, the various characteristics of the asset and projected cash flows. Because this process involves management making estimates with respect to future sales volumes, pricing, new product launches, government reform actions, anticipated cost environment and overall market conditions, and because these estimates form the basis for the determination of whether or not an

impairment charge should be recorded, these estimates are considered to be critical accounting estimates.

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We record contingent consideration resulting from a business acquisition at its estimated fair value on the acquisition date. Each reporting period thereafter, we revalue these obligations and record increases or decreases in their fair value as an adjustment to litigation settlements and other contingencies, net within the Consolidated Statements of Operations. Changes in the fair value of the contingent consideration obligations can result from adjustments to the discount rates, payment periods and adjustments in the probability of achieving future development steps, regulatory approvals, market launches, sales targets and profitability. These fair value measurements represent Level 3 measurements as they are based on significant inputs not observable in the market.

Significant judgment is employed in determining the assumptions utilized as of the acquisition date and for each subsequent measurement period. Accordingly, changes in assumptions described above, could have a material impact on our consolidated results of operations.

Goodwill and intangible assets, including IPR&D, are reviewed for impairment annually and/or when events or other changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Impairment of goodwill and indefinite-lived intangibles, including IPR&D, is determined to exist when the fair value is less than the carrying value of the net assets being tested, with any impairment charge being equal to the difference. Impairment of finite-lived intangibles is determined to exist when undiscounted cash flows related to the assets are less than the carrying value of the assets being tested. Future events and decisions may lead to asset impairment and/or related costs.

Goodwill is allocated and evaluated for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment. The Company has four reporting units, North America Generics, North America Brands, Europe and Rest of World and completes its annual goodwill impairment test as of April 1st. As of April 1, 2018, the date of our most recent annual impairment test, the allocation of the Company's total goodwill was as follows: North America Generics \$2.89 billion, North America Brands \$660.0 million, Europe \$4.97 billion and Rest of World \$1.80 billion.

The Company performed a quantitative impairment analysis for all of its reporting units as of April 1, 2018. The impairment analysis consists of a comparison of the estimated fair value of the individual reporting units with their carrying amount, including goodwill. In estimating each reporting unit's fair value, we performed extensive valuation analysis utilizing both income and market-based approaches, in our goodwill assessment process. We utilized an average of the two methods in estimating the fair value of the individual reporting units, except for the North America Brands reporting unit where the fair value was estimated utilizing the income approach. The following describes the valuation methodologies used to derive the estimated fair value of the reporting units.

Income Approach: Under this approach, to determine fair value, we discounted the expected future cash flows of each reporting unit. We used a discount rate, which reflected the overall level of inherent risk and the rate of return an outside investor would have expected to earn. To estimate cash flows beyond the final year of our model, we used a terminal value approach. Under this approach, we used EBITDA in the final year of our model, adjusted to estimate a normalized cash flow, applied a perpetuity growth assumption, and discounted by a perpetuity discount factor to determine the terminal value. We incorporated the present value of the resulting terminal value into our estimate of fair value.

Market-Based Approach: The Company also utilizes a market-based approach to estimate fair value, principally utilizing the guideline company method which focuses on comparing our risk profile and growth prospects to a select group of publicly traded companies with reasonably similar guidelines.

As of April 1, 2018, the Company determined that the fair value of the North America Generics, North America Brands and Rest of World reporting units was substantially in excess of the respective unit's carrying value. For the Europe reporting unit, the estimated fair value exceeded its carrying value by approximately \$800.0 million or 6%. The excess fair value for the Europe reporting unit is consistent with the result of the Company's 2017 annual impairment test. As it relates to the income approach for the Europe reporting unit at April 1, 2018, the Company forecasted cash flows for the next 5 years. During the forecast period, the revenue compound annual growth rate was approximately 3.5%. A terminal value year was calculated with a 2.0% revenue growth rate applied. The discount rate utilized was 9.0% and the estimated tax rate was 24.0%. Under the market-based approach, we utilized an estimated

range of market multiples of 9.0 to 10.5 times EBITDA plus a control premium of 15.0%. If all other assumptions are held constant, a reduction in the terminal value growth rate by 2.0% or an increase in discount rate by 1.5% would result in an impairment charge for the Europe reporting unit.

The determination of the fair value of the reporting units requires us to make significant estimates and assumptions that affect the reporting unit's expected future cash flows. These estimates and assumptions primarily include, but are not limited to, market multiples, control premiums, the discount rate, terminal growth rates, operating income before depreciation and amortization, and capital expenditures forecasts. Due to the inherent uncertainty involved in making these estimates, actual

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results could differ from those estimates. In addition, changes in underlying assumptions, especially as it relates to the key assumptions detailed, could have a significant impact on the fair value of the reporting units.

We have also assessed the recoverability of certain long-lived assets, principally finite-lived intangible assets, contained within the reporting units whenever certain impairment indicators are present. Any impairment of these assets must be considered prior to our impairment review of goodwill. The assessment for impairment is based on our ability to recover the carrying value of the long-lived assets or asset grouping by analyzing the expected future undiscounted pre-tax cash flows specific to the asset or asset grouping. If the carrying amount is greater than the undiscounted cash flows, the Company recognizes an impairment loss for the carrying amount over the estimated fair value based on the discounted cash flows.

Significant management judgment is involved in estimating the recoverability of these assets and is dependent upon the accuracy of the assumptions used in making these estimates, as well as how the estimates compare to the eventual future operating performance of the specific asset or asset grouping. For the years ended December 31, 2018, 2017 and 2016, the Company recorded \$106.3 million, \$6.2 million, and \$18.4 million, respectively, of impairment charges for finite-lived intangible assets, which were recorded as a component of amortization expense. At December 31, 2018 and 2017, the Company's finite-lived intangible assets totaled \$13.04 billion and \$14.43 billion, respectively. Changes to any of the Company's assumptions related to the estimated fair value based on the discounted cash flows, including discount rates or the competitive environment related to the assets, could lead to future material impairment charges. Any future long-lived assets impairment charges could have a material impact the on Company's consolidated financial condition and results of operations.

The Company's IPR&D assets are tested at least annually for impairment, but they may be tested whenever certain impairment indicators are present. Impairment is determined to exist when the fair value of IPR&D assets, which was based upon updated forecasts and commercial development plans, is less than the carrying value of the assets being tested. For the years ended December 31, 2018, 2017 and 2016, the Company recorded \$117.7 million, \$74.6 million, and \$49.9 million, respectively, of impairment charges, which were recorded as a component of amortization expense. At December 31, 2018 and 2017, the Company's IPR&D assets totaled \$625.6 million and \$813.2 million, respectively.

The fair value of both IPR&D and finite-lived intangible assets was determined based upon detailed valuations employing the income approach which utilized Level 3 inputs, as defined in Note 8 Financial Instruments and Risk Management included in Item 8 in this Annual Report on Form 10-K. Changes to any of the Company's assumptions including changes to or abandonment of development programs, regulatory timelines, discount rates or the competitive environment related to the assets could lead to future material impairment charges.

Income Taxes

We compute our income taxes based on the statutory tax rates and tax reliefs available to Mylan in the various jurisdictions in which we generate income. Significant judgment is required in determining our income taxes and in evaluating our tax positions. We establish reserves in accordance with Mylan's policy regarding accounting for uncertainty in income taxes. Our policy provides that the tax effects from an uncertain tax position be recognized in Mylan's financial statements, only if the position is more likely than not of being sustained upon audit, based on the technical merits of the position. We adjust these reserves in light of changing facts and circumstances, such as the settlement of a tax audit. Our provision for income taxes includes the impact of reserve provisions and changes to reserves. Favorable resolution would be recognized as a reduction to our provision for income taxes in the period of resolution or expiration of the underlying statutes of limitation. Based on this evaluation, as of December 31, 2018, our reserve for unrecognized tax benefits totaled \$96.3 million.

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred in certain taxing jurisdictions over the three-year period ended December 31, 2018. Such objective evidence limits the ability to consider other subjective evidence such as our projections for future growth.

Based on this evaluation and other factors, as of December 31, 2018, a valuation allowance of \$806.0 million has been recorded in order to measure only the portion of the deferred tax asset that more likely than not will be realized. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or if objective negative evidence in the form of cumulative losses is no longer present and additional weight may be given to subjective evidence such as projections for growth. When assessing the realizability of deferred tax assets, management considers all available evidence, including historical information, long-term forecasts of future taxable income and possible tax planning strategies. Amounts recorded for valuation allowances can result from a complex series of estimates, assumptions and judgments about future events. Due to the inherent uncertainty involved in making these estimates, assumptions and judgments, actual results could differ materially. Any future increases to the Company's valuation

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allowances could materially impact the Company's consolidated financial condition and results of operations. At December 31, 2018 and 2017, the Company's net deferred tax assets totaled \$572.2 million and \$496.8 million, respectively.

On December 22, 2017, the Tax Act was signed into law making significant changes to the Code. Changes include, but are not limited to, a U.S. federal corporate income tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, the partial transition of U.S. international taxation from a worldwide tax system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings of non-U.S. corporate subsidiaries of large U.S. shareholders as of December 31, 2017. A variance of 5% between estimated reserves and valuation allowances and actual resolution and realization of these tax items would have an effect on our reserve balance and valuation allowance of approximately \$45.3 million.

Legal Matters

Mylan is involved in various legal proceedings, some of which involve claims for substantial amounts. An estimate is made to accrue for a loss contingency relating to any of these legal proceedings if it is probable that a liability was incurred as of the date of the financial statements and the amount of loss can be reasonably estimated. Because of the subjective nature inherent in assessing the outcome of litigation and because of the potential that an adverse outcome in a legal proceeding could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price, such estimates are considered to be critical accounting estimates.

A variance of 5% between estimated and recorded litigation reserves and actual resolution of certain legal matters would have an effect on our litigation reserve balance of approximately \$2.7 million. Refer to Note 19 Litigation included in Item 8 in this Annual Report on Form 10-K for further discussion of litigation matters.

Recent Accounting Pronouncements

Refer to Note 2 Summary of Significant Accounting Policies in Item 8 in this Annual Report on Form 10-K for recently adopted accounting pronouncements and recently issued accounting pronouncements not yet adopted.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

Foreign Currency Exchange Risk

A significant portion of our revenues and earnings are exposed to changes in foreign currency exchange rates. We seek to manage this foreign exchange risk in part through operational means, including managing same currency revenues in relation to same currency costs and same currency assets in relation to same currency liabilities.

From time to time, foreign exchange risk is managed through the use of foreign currency forward-exchange contracts. These contracts are used to offset the potential earnings effects from mostly intercompany foreign currency assets and liabilities that arise from operations and from intercompany loans. Mylan's primary areas of foreign exchange risk relative to the U.S. Dollar are the Euro, Swedish Krona, Indian Rupee, Japanese Yen, Australian Dollar, Canadian Dollar, Pound Sterling and Brazilian Real. Any unhedged foreign exchange exposures continue to be subject to market fluctuations.

Our financial instrument holdings at year end were analyzed to determine their sensitivity to foreign exchange rate changes. The fair values of these instruments were determined as follows:

foreign currency forward-exchange contracts — net present values

foreign currency denominated receivables, payables, debt and loans — changes in exchange rates

In this sensitivity analysis, we assumed that the change in one currency's rate relative to the U.S. Dollar would not have an effect on other currencies' rates relative to the U.S. Dollar. All other factors were held constant.

If there were an adverse change in foreign currency exchange rates of 10%, the expected net effect on net income related to Mylan's foreign currency denominated financial instruments would not be material.

The Company is also exposed to translation risk on non-U.S. dollar-denominated net assets. Non-U.S. dollar borrowings, principally our Euro denominated long-term debt, are used to hedge the foreign currency exposures of our net investment in certain foreign affiliates and are designated as hedges of net investments. The foreign exchange gains or losses on these hedges is included in the foreign currency translation component of accumulated other comprehensive income/(loss). If

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our net investment decreases below the equivalent value of the non-U.S. debt borrowings, the change in the remeasurement basis of the debt would be subject to recognition in net income as changes occur.

Interest Rate and Long-Term Debt Risk

Mylan's exposure to interest rate risk arises primarily from our U.S. Dollar and Euro borrowings and U.S. Dollar investments. We invest primarily on a variable-rate basis and we borrow on both a fixed and variable basis. In order to maintain a certain ratio of fixed to variable rate debt, from time to time, depending on market conditions, Mylan will use derivative financial instruments such as interest rate swaps to fix interest rates on variable-rate borrowings or to convert fixed-rate borrowings to variable interest rates.

As of December 31, 2018, Mylan's long-term fixed rate borrowings consist principally of \$12.5 billion notional amount of senior notes and Euro notes. Generally, the fair value of fixed interest rate debt will decrease as interest rates rise and increase as interest rates fall. As of December 31, 2018, the fair value of our outstanding fixed rate senior notes and Euro notes was approximately \$13.1 billion. A 100 basis point change in interest rates on Mylan's variable rate debt, net of interest rate swaps, would result in a change in interest expense of approximately \$14.3 million per year.

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ITEM 8. Financial Statements And Supplementary Data
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Management's Report on Internal Control over Financial Reporting

Management of Mylan N.V. (the "Company") is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. In order to evaluate the effectiveness of internal control over financial reporting, management has conducted an assessment, including testing, using the criteria in Internal Control - Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

As a result of this assessment, management has concluded that the Company maintained effective internal control over financial reporting as of December 31, 2018 based on the criteria in Internal Control - Integrated Framework (2013) issued by COSO.

Our independent registered public accounting firm, Deloitte & Touche LLP, has audited the effectiveness of the Company's internal control over financial reporting. Deloitte & Touche LLP's opinion on the Company's internal control over financial reporting appears on page 73 of this Annual Report on Form 10-K.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Mylan N.V.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Mylan N.V. and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive earnings, equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and the consolidated financial statement schedule listed in the Index at Item 15 (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 26, 2019, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP
Pittsburgh, Pennsylvania
February 26, 2019

We have served as the Company's auditor since 1976.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Mylan N.V.:

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Mylan N.V. and subsidiaries (the “Company”) as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2018, of the Company and our report dated February 26, 2019, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ DELOITTE & TOUCHE LLP

Pittsburgh, Pennsylvania

February 26, 2019

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MYLAN N.V. AND SUBSIDIARIES

Consolidated Balance Sheets

(In millions, except share and per share amounts)

| | December 31, 2018 | December 31, 2017 |
|---|----------------------|----------------------|
| ASSETS | | |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 388.1 | \$ 292.1 |
| Accounts receivable, net | 2,881.0 | 3,612.4 |
| Inventories | 2,580.2 | 2,542.7 |
| Prepaid expenses and other current assets | 518.4 | 766.1 |
| Total current assets | 6,367.7 | 7,213.3 |
| Property, plant and equipment, net | 2,170.2 | 2,339.1 |
| Intangible assets, net | 13,664.6 | 15,245.8 |
| Goodwill | 9,747.8 | 10,205.7 |
| Deferred income tax benefit | 572.2 | 496.8 |
| Other assets | 212.4 | 305.6 |
| Total assets | \$ 32,734.9 | \$ 35,806.3 |
| LIABILITIES AND EQUITY | | |
| Liabilities | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,617.0 | \$ 1,452.5 |
| Short-term borrowings | 1.9 | 46.5 |
| Income taxes payable | 121.5 | 112.9 |
| Current portion of long-term debt and other long-term obligations | 699.8 | 1,808.9 |
| Other current liabilities | 2,147.6 | 2,964.5 |
| Total current liabilities | 4,587.8 | 6,385.3 |
| Long-term debt | 13,161.2 | 12,865.3 |
| Deferred income tax liability | 1,722.0 | 2,012.4 |
| Other long-term obligations | 1,096.8 | 1,235.7 |
| Total liabilities | 20,567.8 | 22,498.7 |
| Equity | | |
| Mylan N.V. shareholders' equity | | |
| Ordinary shares — nominal value €0.01 per share as of December 31, 2018 and December 31, 2017 | | |
| Shares authorized: 1,200,000,000 | | |
| Shares issued: 539,289,665 and 537,902,426 as of December 31, 2018 and December 31, 2017 | 6.0 | 6.0 |
| Additional paid-in capital | 8,591.4 | 8,586.0 |
| Retained earnings | 6,010.7 | 5,644.5 |
| Accumulated other comprehensive loss | (1,441.3) | (361.2) |
| | 13,166.8 | 13,875.3 |
| Less: Treasury stock — at cost | | |
| Ordinary shares: 23,490,867 and 13,695,251 as of December 31, 2018 and December 31, 2017 | 999.7 | 567.7 |
| Total equity | 12,167.1 | 13,307.6 |
| Total liabilities and equity | \$ 32,734.9 | \$ 35,806.3 |

See Notes to Consolidated Financial Statements

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MYLAN N.V. AND SUBSIDIARIES
 Consolidated Statements of Operations
 (In millions, except per share amounts)

| | Year Ended December 31, | | |
|--|-------------------------|------------|------------|
| | 2018 | 2017 | 2016 |
| Revenues: | | | |
| Net sales | \$11,268.7 | \$11,760.0 | \$10,967.1 |
| Other revenues | 165.2 | 147.7 | 109.8 |
| Total revenues | 11,433.9 | 11,907.7 | 11,076.9 |
| Cost of sales | 7,432.3 | 7,124.6 | 6,379.9 |
| Gross profit | 4,001.6 | 4,783.1 | 4,697.0 |
| Operating expenses: | | | |
| Research and development | 704.5 | 783.3 | 826.8 |
| Selling, general and administrative | 2,441.0 | 2,575.7 | 2,498.5 |
| Litigation settlements and other contingencies, net | (49.5) |) (13.1) |) 672.5 |
| Total operating expenses | 3,096.0 | 3,345.9 | 3,997.8 |
| Earnings from operations | 905.6 | 1,437.2 | 699.2 |
| Interest expense | 542.3 | 534.6 | 454.8 |
| Other expense (income), net | 64.9 | (0.4) |) 122.7 |
| Earnings before income taxes | 298.4 | 903.0 | 121.7 |
| Income tax (benefit) provision | (54.1) |) 207.0 | (358.3) |
| Net earnings | 352.5 | 696.0 | 480.0 |
| Earnings per ordinary share attributable to Mylan N.V. ordinary shareholders | | | |
| Basic | \$0.69 | \$1.30 | \$0.94 |
| Diluted | \$0.68 | \$1.30 | \$0.92 |
| Weighted average ordinary shares outstanding: | | | |
| Basic | 514.5 | 534.5 | 513.0 |
| Diluted | 516.5 | 536.7 | 520.5 |

See Notes to Consolidated Financial Statements

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MYLAN N.V. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Earnings

(In millions)

| | Year Ended December 31, | | |
|--|-------------------------|-----------|-----------|
| | 2018 | 2017 | 2016 |
| Net earnings | \$352.5 | \$696.0 | \$480.0 |
| Other comprehensive (loss) earnings, before tax: | | | |
| Foreign currency translation adjustment | (1,125.2) | 2,103.9 | (507.4) |
| Change in unrecognized (loss) gain and prior service cost related to defined benefit plans | (3.8) | 3.8 | 21.4 |
| Net unrecognized (loss) gain on derivatives in cash flow hedging relationships | (79.2) | 52.7 | (31.2) |
| Net unrecognized gain (loss) on derivatives in net investment hedging relationships | 111.6 | (238.4) | (1.8) |
| Net unrealized (loss) gain on marketable securities | (0.1) | (6.7) | 24.6 |
| Other comprehensive (loss) earnings, before tax | (1,096.7) | 1,915.3 | (494.4) |
| Income tax (benefit) provision | (24.1) | 12.8 | 5.0 |
| Other comprehensive (loss) earnings, net of tax | (1,072.6) | 1,902.5 | (499.4) |
| Comprehensive (loss) earnings | \$(720.1) | \$2,598.5 | \$(19.4) |

See Notes to Consolidated Financial Statements

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MYLAN N.V. AND SUBSIDIARIES

Consolidated Statements of Equity

(In millions, except share amounts)

| | Ordinary Shares | Cost | Additional Paid-In Capital | Retained Earnings | Treasury Stock Shares | Cost | Accumulated Other Comprehensive Loss | Noncontrol- ling Interest | Total Equity |
|--|-----------------|-------|----------------------------------|----------------------|--------------------------|-----------|---|---------------------------------|-----------------|
| Balance at December 31, 2015 | 491,928,095 | \$5.5 | \$7,128.6 | \$4,462.1 | 1,311,193 | \$(67.5) | \$(1,764.3) | \$ 1.4 | \$9,765.8 |
| Net earnings | — | — | — | 480.0 | — | — | — | — | 480.0 |
| Other comprehensive loss, net of tax | — | — | — | — | — | — | (499.4) | — | (499.4) |
| Issuance of restricted stock and stock options exercised, net | 1,283,580 | — | 13.6 | — | — | — | — | — | 13.6 |
| Share-based compensation expense | — | — | 88.9 | — | — | — | — | — | 88.9 |
| Taxes related to the net share settlement of equity awards | — | — | (14.2) | — | — | — | — | — | (14.2) |
| Tax benefit of stock option plans | — | — | 1.2 | — | — | — | — | — | 1.2 |
| Shares issued for warrant settlement | 16,979,984 | 0.2 | (0.2) | — | — | — | — | — | — |
| Issuance of ordinary shares to purchase Meda | 26,447,632 | 0.3 | 1,281.4 | — | — | — | — | — | 1,281.7 |
| Balance at December 31, 2016 | 536,639,291 | \$6.0 | \$8,499.3 | \$4,942.1 | 1,311,193 | \$(67.5) | \$(2,263.7) | \$ 1.4 | \$11,117.6 |
| Net earnings | — | \$— | \$— | \$696.0 | — | \$— | \$— | \$— | \$696.0 |
| Other comprehensive earnings, net of tax | — | — | — | — | — | — | 1,902.5 | — | 1,902.5 |
| Issuance of restricted stock and stock options exercised, net | 1,263,135 | — | 17.8 | — | — | — | — | — | 17.8 |
| Share-based compensation expense | — | — | 74.7 | — | — | — | — | — | 74.7 |
| Ordinary share repurchase | — | — | — | — | 12,384,058 | (500.2) | — | — | (500.2) |
| Taxes related to the net share | — | — | (5.8) | — | — | — | — | — | (5.8) |

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| | | | | | | | | | |
|---|-------------|-------|-----------|-----------|------------|-----------|------------|--------|------------|
| settlement of equity awards | | | | | | | | | |
| Other | — | — | — | 6.4 | — | — | — | (1.4 |) 5.0 |
| Balance at December 31, 2017 | 537,902,426 | \$6.0 | \$8,586.0 | \$5,644.5 | 13,695,251 | \$(567.7) | \$(361.2 |) \$ — | \$13,307.6 |
| Net earnings | — | \$— | \$— | \$352.5 | — | \$— | \$— | \$ — | \$352.5 |
| Other comprehensive loss, net of tax | — | — | — | — | — | — | (1,072.6 |) — | (1,072.6) |
| Ordinary share repurchase | — | — | — | — | 9,795,616 | (432.0 |) — | — | (432.0) |
| Share-based compensation (income) expense | — | — | (3.3 |) — | — | — | — | — | (3.3) |
| Issuance of restricted stock and stock options exercised, net | 1,387,239 | — | 17.7 | — | — | — | — | — | 17.7 |
| Taxes related to the net share settlement of equity awards | — | — | (9.0 |) — | — | — | — | — | (9.0) |
| Cumulative effect of the adoption of new accounting standards | — | — | — | 13.7 | — | — | (7.5 |) — | 6.2 |
| Balance at December 31, 2018 | 539,289,665 | \$6.0 | \$8,591.4 | \$6,010.7 | 23,490,867 | \$(999.7) | \$(1,441.3 |) \$ — | \$12,167.1 |

See Notes to Consolidated Financial Statements

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MYLAN N.V. AND SUBSIDIARIES
 Consolidated Statements of Cash Flows
 (In millions)

| | Year Ended December 31, | | |
|---|-------------------------|------------|------------|
| | 2018 | 2017 | 2016 |
| Cash flows from operating activities: | | | |
| Net earnings | \$352.5 | \$696.0 | \$480.0 |
| Adjustments to reconcile net earnings to net cash provided by operating activities: | | | |
| Depreciation and amortization | 2,109.9 | 1,805.8 | 1,523.0 |
| Deferred income tax benefit | (264.3) | (111.4) | (609.5) |
| Litigation settlements and other contingencies, net | (31.6) | (40.1) | 597.7 |
| Unrealized losses on acquisition-related foreign currency derivatives | — | — | 128.6 |
| Loss from equity method investments | 78.7 | 58.0 | 112.8 |
| Share-based compensation (income) expense | (3.3) | 74.7 | 88.9 |
| Write off of financing fees | 2.7 | 3.2 | 35.8 |
| Other non-cash items | 286.1 | 261.0 | 499.4 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | 340.1 | (162.2) | (131.8) |
| Inventories | (547.6) | (129.5) | (279.3) |
| Trade accounts payable | 220.3 | 14.4 | 87.7 |
| Income taxes | (23.9) | 15.2 | 37.5 |
| Other operating assets and liabilities, net | (177.9) | (420.3) | (523.6) |
| Net cash provided by operating activities | 2,341.7 | 2,064.8 | 2,047.2 |
| Cash flows from investing activities: | | | |
| Cash paid for acquisitions, net of cash acquired | (65.9) | (167.0) | (6,481.9) |
| Capital expenditures | (252.1) | (275.9) | (390.4) |
| Payments for product rights and other, net | (943.5) | (620.3) | (360.2) |
| Cash paid for Meda's unconditional deferred payment | — | — | (308.0) |
| Settlement of acquisition-related foreign currency derivatives | — | — | (128.6) |
| Proceeds from sale of assets and subsidiaries | 29.3 | 86.7 | — |
| Purchase of marketable securities | (63.4) | (96.5) | (30.2) |
| Proceeds from the sale of marketable securities | 85.2 | 96.6 | 21.5 |
| Net cash used in investing activities | (1,210.4) | (976.4) | (7,677.8) |
| Cash flows from financing activities: | | | |
| Proceeds from issuance of long-term debt | 2,577.9 | 876.1 | 11,752.2 |
| Payments of long-term debt | (3,165.2) | (2,232.7) | (6,296.3) |
| Payments of financing fees | (21.4) | (10.1) | (112.6) |
| Change in short-term borrowings, net | (44.4) | (2.9) | 40.8 |
| Purchase of ordinary shares | (432.0) | (500.2) | — |
| Proceeds from exercise of stock options | 17.8 | 17.8 | 13.8 |
| Taxes paid related to net share settlement of equity awards | (10.1) | (7.4) | (17.5) |
| Contingent consideration payments | (11.9) | (26.1) | (35.5) |
| Acquisition of noncontrolling interest | (0.6) | (7.5) | (1.1) |
| Other items, net | (1.0) | (0.1) | 0.8 |
| Net cash (used in) provided by financing activities | (1,090.9) | (1,893.1) | 5,344.6 |
| Effect on cash of changes in exchange rates | (21.0) | 27.6 | (9.6) |
| Net increase (decrease) in cash, cash equivalents and restricted cash | 19.4 | (777.1) | (295.6) |
| Cash, cash equivalents and restricted cash — beginning of period | 369.9 | 1,147.0 | 1,442.6 |

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| | | | |
|--|---------|---------|-----------|
| Cash, cash equivalents and restricted cash — end of period | \$389.3 | \$369.9 | \$1,147.0 |
| Supplemental disclosures of cash flow information — | | | |
| Non-cash transactions: | | | |
| Contingent consideration | \$— | \$4.0 | \$16.0 |
| Ordinary shares issued for acquisition | \$— | \$— | \$1,281.7 |
| Cash paid during the period for: | | | |
| Income taxes | \$228.6 | \$285.7 | \$285.6 |
| Interest | \$460.8 | \$474.0 | \$357.2 |

See Notes to Consolidated Financial Statements

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Mylan N.V. and Subsidiaries

Notes to Consolidated Financial Statements

1. Nature of Operations

Mylan N.V. and its subsidiaries (collectively, the “Company,” “Mylan,” “our” or “we”) are engaged in the global development, licensing, manufacture, marketing and distribution of generic, branded generic, brand-name and over-the-counter (“OTC”) pharmaceutical products for resale by others and active pharmaceutical ingredients (“API”) through three reportable segments on a geographic basis, North America, Europe and Rest of World. Our North America segment comprises our operations in the United States (“U.S.”) and Canada. Our Europe segment encompasses our operations across 35 countries within the region, including France, Italy, Germany, the United Kingdom (the “U.K.”) and Spain. Our Rest of World segment reflects our operations in more than 120 countries, including our operations in Japan, Australia, China, Brazil, Russia, India, South Africa, and certain markets in the Middle East and Southeast Asia. Our API business is conducted through Mylan Laboratories Limited (“Mylan India”), which is included within our Rest of World segment.

2. Summary of Significant Accounting Policies

Principles of Consolidation. The Consolidated Financial Statements include the accounts of Mylan and those of its wholly owned and majority-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Investments in equity method affiliates are recorded at cost and adjusted for the Company’s share of the affiliates’ cumulative results of operations, capital contributions and distributions. Noncontrolling interests in the Company’s subsidiaries are generally recorded net of tax as net earnings attributable to noncontrolling interests.

Use of Estimates in the Preparation of Financial Statements. The preparation of financial statements, in conformity with accounting principles generally accepted in the U.S. (“U.S. GAAP”), requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Because of the uncertainty inherent in such estimates, actual results could differ from those estimates.

Foreign Currencies. The Consolidated Financial Statements are presented in U.S. Dollars, the reporting currency of Mylan. Statements of Operations and Cash Flows of all of the Company’s subsidiaries that have functional currencies other than U.S. Dollars are translated at a weighted average exchange rate for the period for inclusion in the Consolidated Statements of Operations and Cash Flows, whereas assets and liabilities are translated at the end of the period exchange rates for inclusion in the Consolidated Balance Sheets. Translation differences are recorded directly in shareholders’ equity as foreign currency translation adjustments. Gains or losses on transactions denominated in a currency other than the subsidiaries’ functional currency, which arise as a result of changes in foreign currency exchange rates, are recorded in the Consolidated Statements of Operations.

Cash and Cash Equivalents. Cash and cash equivalents are comprised of highly liquid investments with an original maturity of three months or less at the date of purchase.

Debt and Equity Securities. On January 1, 2018, the Company adopted Accounting Standards Update 2016-01, Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities (“ASU 2016-01”) which requires all equity securities to be measured at fair value with changes recognized through net income (loss). Debt securities classified as available-for-sale are recorded at fair value, with net unrealized gains and losses, net of income taxes, reflected in accumulated other comprehensive loss as a component of shareholders’ equity. Net realized gains and losses on sales of available-for-sale debt securities are computed on a specific security basis and are included in other expense, net, in the Consolidated Statements of Operations. Debt securities, and marketable equity securities prior to January 1, 2018, classified as trading securities are valued using quoted stock prices from public exchanges, the quoted market price from broker or dealer quotations or transparent pricing sources at the reporting date. Realized and unrealized gains and losses are included in other expense, net, in the Consolidated Statements of Operations.

Concentrations of Credit Risk. Financial instruments that potentially subject the Company to credit risk consist principally of interest-bearing investments, derivatives and accounts receivable.

Mylan invests its excess cash in high-quality, liquid money market instruments, principally overnight deposits and highly rated money market funds. The Company maintains deposit balances at certain financial institutions in excess of federally insured amounts. Periodically, the Company reviews the creditworthiness of its counterparties to derivative

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transactions, and it does not expect to incur a loss from failure of any counterparties to perform under agreements it has with such counterparties.

Inventories. Inventories are stated at the lower of cost or market, with cost principally determined by the first-in, first-out method. Provisions for potentially obsolete or slow-moving inventory, including pre-launch inventory, are made based on our analysis of product dating, inventory levels, historical obsolescence and future sales forecasts.

Included as a component of cost of sales is expense related to the net realizable value of inventories.

Property, Plant and Equipment. Property, plant and equipment are stated at cost less accumulated depreciation.

Depreciation is computed and recorded on a straight-line basis over the assets' estimated service lives (3 to 18 years for machinery and equipment and other fixed assets and 15 to 39 years for buildings and improvements). Capitalized software is included in property, plant and equipment and is amortized over estimated useful lives ranging from 3 to 7 years.

Intangible Assets and Goodwill. Intangible assets are stated at cost less accumulated amortization. Amortization is generally recorded on a straight-line basis over estimated useful lives ranging from 3 to 20 years. The Company periodically reviews the estimated useful lives of intangible assets and makes adjustments when events indicate that a shorter life is appropriate.

The Company accounts for acquired businesses using the acquisition method of accounting in accordance with the provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 805, which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective fair values. The cost to acquire a business is allocated to the underlying net assets of the acquired business in proportion to their respective fair values. Amounts allocated to acquired in-process research and development ("IPR&D") are capitalized at the date of acquisition and are not amortized. As products in development are approved for sale, amounts are allocated to product rights and licenses and amortized over their estimated useful lives. Finite-lived intangible assets are amortized over the expected life of the asset. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

Purchases of developed products and licenses that are accounted for as an asset acquisition are capitalized as intangible assets and amortized over an estimated useful life. IPR&D assets acquired as part of an asset acquisition are expensed immediately if they have no alternative future uses.

The Company reviews goodwill for impairment at least annually or more frequently if events or changes in circumstances indicate that the carrying value of goodwill may not be recoverable based on management's assessment of the fair value of the Company's reporting units as compared to their related carrying value. Under the authoritative guidance issued by the FASB, we have the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative goodwill impairment test. If we determine that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then the goodwill impairment test is performed. The goodwill impairment test requires the Company to estimate the fair value of the reporting unit and to compare the fair value of the reporting unit with its carrying amount. If the carrying amount is less than its fair value then there is no impairment recognized. If the carrying value recorded exceeds the fair value calculated, an impairment charge is recorded for the difference. The judgments made in determining the projected cash flows used to estimate the fair value can materially impact the Company's financial condition and results of operations.

Indefinite-lived intangibles, principally IPR&D, are tested at least annually for impairment or upon the occurrence of a triggering event. The impairment test for IPR&D consists of a comparison of the asset's fair value with its carrying value. Impairment is determined to exist when the fair value is less than the carrying value of the assets being tested in an amount of the difference.

Contingent Consideration. Mylan records contingent consideration resulting from business acquisitions at fair value on the acquisition date. Each reporting period thereafter, the Company revalues these obligations and records increases or decreases in their fair value as a charge (credit) to litigation settlements and other contingencies, net within the Consolidated Statements of Operations. Changes in the fair value of the contingent consideration obligations can result from adjustments to the discount rates, payment periods and adjustments in the probability of

achieving future development steps, regulatory approvals, market launches, sales targets and profitability. These fair value measurements represent Level 3 measurements, as they are based on significant inputs not observable in the market.

Significant judgment is employed in determining the assumptions utilized as of the acquisition date and for each subsequent measurement period. Accordingly, changes in the assumptions described above could have a material impact on the Company's consolidated financial condition and results of operations.

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Impairment of Long-Lived Assets. The carrying values of long-lived assets, which include property, plant and equipment and intangible assets with finite lives, are evaluated periodically in relation to the expected future undiscounted cash flows of the underlying assets and monitored for other potential triggering events. The assessment for impairment is based on our ability to recover the carrying value of the long-lived assets or asset grouping by analyzing the expected future undiscounted pre-tax cash flows specific to the asset or asset grouping. If the carrying amount is greater than the undiscounted cash flows, the Company recognizes an impairment loss for the excess of the carrying amount over the estimated fair value based on the discounted cash flows.

Significant management judgment is involved in estimating the recoverability of these assets and is dependent upon the accuracy of the assumptions used in making these estimates, as well as how the estimates compare to the eventual future operating performance of the specific asset or asset grouping. Any future long-lived assets impairment charges could have a material impact on the Company's consolidated financial condition and results of operations.

Short-Term Borrowings. The Company's subsidiaries in India have working capital facilities with several banks which are secured by its current assets. Mylan Pharmaceuticals Inc. ("MPI"), a wholly owned subsidiary of the Company, also has a \$400 million accounts receivable facility ("Receivables Facility"), which will expire in March 2019.

Revenue Recognition. On January 1, 2018, the Company adopted ASC Topic 606 Revenue from Contracts with Customers ("ASC 606") using the modified retrospective method applied to those contracts which were not completed as of the date of adoption. Results for reporting periods beginning on January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with ASC Topic 605 Revenue Recognition ("ASC 605"). Under ASC 605, the Company recognized net sales when title and risk of loss passed to its customers and when provisions for estimates, as described below, were reasonably determinable.

Under ASC 606, the Company recognizes net revenue for product sales when control of the promised goods or services is transferred to our customers in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. Revenues are recorded net of provisions for variable consideration, including discounts, rebates, governmental rebate programs, price adjustments, returns, chargebacks, promotional programs and other sales allowances. Accruals for these provisions are presented in the consolidated financial statements as reductions in determining net sales and as a contra asset in accounts receivable, net (if settled via credit) and other current liabilities (if paid in cash). The following briefly describes the nature of our provisions for variable consideration and how such provisions are estimated:

Chargebacks: the Company has agreements with certain indirect customers, such as independent pharmacies, retail pharmacy chains, managed care organizations, hospitals, nursing homes, governmental agencies and pharmacy benefit managers, which establish contract prices for certain products. The indirect customers then independently select a wholesaler from which to purchase the products at these contracted prices. Alternatively, certain wholesalers may enter into agreements with indirect customers that establish contract pricing for certain products, which the wholesalers provide. Under either arrangement, Mylan will provide credit to the wholesaler for any difference between the contracted price with the indirect party and the wholesaler's invoice price. Such credits are called chargebacks. The provision for chargebacks is based on expected sell-through levels by our wholesaler customers to indirect customers, as well as estimated wholesaler inventory levels.

Rebates, promotional programs and other sales allowances: this category includes rebate and other programs to assist in product sales. These programs generally provide that the customer receives credit directly related to the amount of purchases or credits upon the attainment of pre-established volumes. Also included in this category are prompt pay discounts, administrative fees and price adjustments to reflect decreases in the selling prices of products.

Returns: consistent with industry practice, Mylan maintains a return policy that allows customers to return a product, which varies country by country in accordance with local practices, generally within a specified period prior (six months) and subsequent (twelve months) to the expiration date. The Company's estimate of the provision for returns is generally based upon historical experience with actual returns.

Governmental rebate programs: government reimbursement programs include Medicare, Medicaid, and State Pharmacy Assistance Programs established according to statute, regulations and policy. Manufacturers of pharmaceutical products that are covered by the Medicaid program are required to pay rebates to each state based on a

statutory formula set forth in the Social Security Act. Medicare beneficiaries are eligible to obtain discounted prescription drug coverage from private sector providers. In addition, certain states have also implemented supplemental rebate programs that obligate manufacturers to pay rebates in excess of those required under federal law. Our estimate of these rebates is based on the historical trends of rebates paid as well as on changes in wholesaler inventory levels and increases or decreases in the level of sales. Also, this provision includes price reductions that are mandated by law outside of the U.S.

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Wholesaler and distributor inventory levels of our products can fluctuate throughout the year due to the seasonality of certain products, the timing of product demand and other factors. Such fluctuations may impact the comparability of our net sales between periods.

Consideration received from licenses of intellectual property is recorded as revenue. Royalty or profit share amounts, which are based on sales of licensed products or technology, are recorded when the customer's subsequent sales or usages occur. Such consideration is included in other revenue in the Consolidated Statements of Operations.

Research and Development. Research and development ("R&D") expenses are charged to operations as incurred.

Income Taxes. Income taxes have been provided for using an asset and liability approach in which deferred income taxes reflect the tax consequences on future years of events that the Company has already recognized in the financial statements or tax returns. Changes in enacted tax rates or laws may result in adjustments to the recorded tax assets or liabilities in the period that the new tax law is enacted.

Earnings per Ordinary Share. Basic earnings per ordinary share is computed by dividing net earnings attributable to Mylan N.V. ordinary shareholders by the weighted average number of ordinary shares outstanding during the period. Diluted earnings per ordinary share is computed by dividing net earnings attributable to Mylan N.V. ordinary shareholders by the weighted average number of ordinary shares outstanding during the period increased by the number of additional shares that would have been outstanding related to potentially dilutive securities or instruments, if the impact is dilutive.

On August 5, 2016, in conjunction with its acquisition of Meda AB (publ.) ("Meda"), the Company issued approximately 26.4 million Mylan N.V. ordinary shares to Meda shareholders. The impact of the issuance of these ordinary shares is included in the calculation of basic earnings per share. The weighted average impact for the year ended December 31, 2016, was approximately 10.8 million ordinary shares.

The Company was authorized to repurchase up to \$1 billion of the Company's ordinary shares under its repurchase program that was previously approved by the Company's Board of Directors and announced on November 16, 2015, but was not obligated to acquire any particular amount of ordinary shares. During 2018, the Company repurchased approximately 9.8 million ordinary shares at a cost of approximately \$432.0 million. In 2017, the Company repurchased approximately 12.4 million ordinary shares at a cost of approximately \$500.2 million, and in 2016, no ordinary shares were repurchased.

On September 15, 2008, concurrent with the sale of \$575 million aggregate principal amount of Cash Convertible Notes due 2015, Mylan Inc. entered into convertible note hedge and warrant transactions with certain counterparties.

On April 15, 2016, in connection with the expiration and settlement of the warrants, the Company issued approximately 17.0 million Mylan N.V. ordinary shares. The impact of the issuance of these ordinary shares is included in the calculation of basic earnings per share from the date of issuance. The dilutive impact of the warrants, prior to settlement, is included in the calculation of diluted earnings per ordinary share based upon the average market value of the Company's ordinary shares during the period as compared to the exercise price. For the year ended December 31, 2016, warrants included in the calculation of diluted earnings per ordinary share were 4.9 million.

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Basic and diluted earnings per ordinary share attributable to Mylan N.V. are calculated as follows:

Year Ended December 31,

| (In millions, except per share amounts) | 2018 | 2017 | 2016 |
|--|----------|----------|----------|
| Basic earnings attributable to Mylan N.V. ordinary shareholders (numerator): Net earnings attributable to Mylan N.V. ordinary shareholders | \$ 352.5 | \$ 696.0 | \$ 480.0 |
| Shares (denominator): Weighted average ordinary shares outstanding | 514.5 | 534.5 | 513.0 |
| Basic earnings per ordinary share attributable to Mylan N.V. ordinary shareholders | \$ 0.69 | \$ 1.30 | \$ 0.94 |
| Diluted earnings attributable to Mylan N.V. ordinary shareholders (numerator): Net earnings attributable to Mylan N.V. ordinary shareholders | \$ 352.5 | \$ 696.0 | \$ 480.0 |
| Shares (denominator): Weighted average ordinary shares outstanding | 514.5 | 534.5 | 513.0 |
| Share-based awards and warrants | 2.0 | 2.2 | 7.5 |
| Total dilutive shares outstanding | 516.5 | 536.7 | 520.5 |
| Diluted earnings per ordinary share attributable to Mylan N.V. ordinary shareholders | \$ 0.68 | \$ 1.30 | \$ 0.92 |

Additional stock awards and restricted ordinary shares were outstanding during the years ended December 31, 2018, 2017 and 2016 but were not included in the computation of diluted earnings per ordinary share for each respective period because the effect would be anti-dilutive. Excluded shares also include certain share-based compensation awards and restricted ordinary shares whose performance conditions had not been fully met. Such excluded shares and anti-dilutive awards represented 8.9 million, 8.5 million and 7.8 million shares for the years ended December 31, 2018, 2017 and 2016, respectively.

Share-Based Compensation. The fair value of share-based compensation is recognized as expense in the Consolidated Statements of Operations over the vesting period.

Derivatives. From time to time the Company may enter into derivative financial instruments (mainly foreign currency exchange forward contracts, interest rate swaps and purchased equity call options) designed to: 1) hedge the cash flows resulting from existing assets and liabilities and transactions expected to be entered into over the next 24 months in currencies other than the functional currency, 2) hedge the variability in interest expense on floating rate debt, 3) hedge the fair value of fixed-rate notes, 4) hedge against changes in interest rates that could impact future debt issuances, 5) hedge cash or share payments required on conversion of issued convertible notes, 6) hedge a net investment in a foreign operation, or 7) economically hedge the foreign currency exposure associated with the purchase price of non-U.S. acquisitions. Derivatives are recognized as assets or liabilities in the Consolidated Balance Sheets at their fair value. When the derivative instrument qualifies as a cash flow hedge, changes in the fair value are deferred through other comprehensive earnings. If a derivative instrument qualifies as a fair value hedge, the changes in the fair value, as well as the offsetting changes in the fair value of the hedged items, are generally included in interest expense. When such instruments do not qualify for hedge accounting the changes in fair value are recorded in the Consolidated Statements of Operations within other expense, net.

Financial Instruments. The Company's financial instruments consist primarily of short-term and long-term debt, interest rate swaps, forward contracts and option contracts. The Company's financial instruments also include cash and cash equivalents as well as accounts and other receivables and accounts payable, the fair values of which approximate their carrying values. As a policy, the Company does not engage in speculative or leveraged transactions.

The Company uses derivative financial instruments for the purpose of hedging foreign currency and interest rate exposures, which exist as part of ongoing business operations, or to hedge cash, and have been used to hedge share payments required on conversion of issued convertible notes. In addition, the Company has designated certain long-term debt instruments as net investment hedges. The Company carries derivative instruments on the Consolidated Balance Sheets at fair value, determined by reference to market data such as forward rates for currencies, implied volatilities, and interest rate swap yield curves. The accounting for changes in the fair value of a derivative instrument depends on whether it has been designated and qualifies as part of a hedging relationship and, if so, the reason for holding it.

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Recent Accounting Pronouncements.

Accounting Standards Issued Not Yet Adopted

In November 2018, the FASB issued Accounting Standards Update 2018-18 (“ASU 2018-18”), Collaborative Arrangements (Topic 808)—Clarifying the Interaction between Topic 808 and Topic 606. The amendments in ASU 2018-18 make targeted improvements to U.S. GAAP for collaborative arrangements by clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. In addition, unit-of-account guidance in Topic 808 was aligned with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted, including adoption in any interim period. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements and disclosures.

In August 2018, the FASB issued Accounting Standards Update 2018-14 (“ASU 2018-14”), Compensation-Retirement Benefits-Defined Benefit Plans-General (Subtopic 715-20): Disclosure Framework-Changes to the Disclosure Requirements for Defined Benefit Plans. ASU 2018-14 removes certain disclosures that are not considered cost beneficial, clarifies certain required disclosures and added additional disclosures. The new standard is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2020 with early adoption in any interim period permitted. The amendments in ASU 2018-14 would need to be applied on a retrospective basis. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements and disclosures.

In August 2018, the FASB issued Accounting Standards Update 2018-13, Fair Value Measurement (Topic 820) Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement, which modifies the disclosure requirements on fair value measurements. The updated guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted for any removed or modified disclosures. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements and disclosures.

In June 2018, the FASB issued Accounting Standards Update 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity’s adoption date of ASC 606. The Company does not believe the impact of the adoption of this guidance will have a material impact on its consolidated financial statements and disclosures.

In February 2018, the FASB issued Accounting Standards Update 2018-02, Income Statement - Reporting Comprehensive Income, (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the newly enacted federal corporate income tax rate under the comprehensive tax legislation enacted by the U.S. government on December 22, 2017 commonly referred to as the Tax Cuts and Jobs Act (the “Tax Act”). The amount of the reclassification would be the difference between the historical corporate income tax rate and the newly enacted 21% corporate income tax rate. The new standard is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2018 with early adoption in any interim period permitted. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements and disclosures.

In February 2016, the FASB issued Accounting Standards Update 2016-02, Leases (Topic 842) which supersedes FASB Topic 840, Leases (Topic 840) and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach,

classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. In July 2018, the FASB issued Accounting Standards Update 2018-10, Codification Improvements to Topic 842 (Leases), and Accounting Standards Update 2018-11, Leases (Topic 842), Targeted Improvements, which provide (i) narrow amendments to clarify how to apply certain aspects of the new lease standard, (ii) entities with an additional transition method to adopt the new standard, and (iii) lessors with a practical expedient

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for separating components of a contract. In December 2018, the FASB issued Accounting Standards Update 2018-20, Leases (Topic 842): Narrow-Scope Improvements for Lessors, which provides certain narrow-scope improvements to Topic 842 as it relates to lessors. All Accounting Standards Updates related to Topic 842 will be effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company is in the process of finalizing the analysis of its lease portfolio, implementing systems and processes and updating its accounting policies to comply with Topic 842. Based on work completed to date, the Company expects to recognize upon adoption an initial right-of-use asset and lease liability on its consolidated balance sheet of approximately \$220 million to \$260 million.

Adoption of New Accounting Standards

In October 2018, the FASB issued Accounting Standards Update 2018-16 (“ASU 2018-16”), Derivatives and Hedging (Topic 815): Inclusion of the Secured Overnight Financing Rate (“SOFR”) Overnight Index Swap (“OIS”) Rate as a Benchmark Interest Rate for Hedge Accounting Purposes. ASU 2018-16 permits the OIS rate based on SOFR as a U.S. benchmark interest rate for hedge accounting purposes under Topic 815. ASU 2018-16 will be effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018 and is required to be adopted in conjunction with ASU 2017-12 (as defined below) on a prospective basis. The impact of the adoption of this guidance did not have a material impact on the Company’s consolidated financial statements and disclosures.

In August 2017, the FASB issued Accounting Standards Update 2017-12, Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities (“ASU 2017-12”). The objective of this update is to improve the financial reporting of hedging relationships to better portray the economic results of an entity’s risk management activities in its financial statements. The amendments in this update also make certain targeted improvements to simplify the application of the hedge accounting guidance in current U.S. GAAP based on feedback received from preparers, auditors, users, and other stakeholders. This guidance is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted, including adoption in any interim period. The Company elected to early adopt this guidance as of January 1, 2018 and applied it on a prospective basis. Upon adoption, the Company recorded a cumulative effect adjustment.

In May 2017, the FASB issued Accounting Standards Update 2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting (“ASU 2017-09”), which amends the scope of modification accounting for share-based payment arrangements. ASU 2017-09 provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under Topic 718. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions and classification of the awards are the same immediately before and after the modification. As required, the Company applied the provisions of ASU 2017-09 on a prospective basis as of January 1, 2018 and the adoption did not have a material impact on its consolidated financial statements and disclosures.

In March 2017, the FASB issued Accounting Standards Update 2017-07, Compensation - Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost (“ASU 2017-07”), which requires companies to disaggregate the service cost component from the other components of net benefit cost and disclose the amount of net benefit cost that is included in the income statement or capitalized in assets, by line item. This guidance requires companies to report the service cost component in the same line item(s) as other compensation costs and to report other pension-related costs (which include interest costs, amortization of pension-related costs from prior periods and gains or losses on plan assets) separately and exclude them from the subtotal of operating income. This guidance also allows only the service cost component to be eligible for capitalization when applicable. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. This guidance should be applied retrospectively for the presentation of the service cost component and the other components of net periodic pension cost and net periodic postretirement benefit cost in the income statement and prospectively, on and after the effective date, for the capitalization of the service cost component of net periodic pension cost and net periodic postretirement benefit in assets. The update allows a practical expedient that permits a company to use the amounts disclosed in its pension and other postretirement plan note for the prior comparative periods as the estimation basis for applying the retrospective presentation requirements. As

required, the Company applied the provisions of ASU 2017-07 as of January 1, 2018 and the adoption did not have a material impact on its consolidated financial statements and disclosures.

In November 2016, the FASB issued Accounting Standards Update 2016-18, Statement of Cash Flows (Topic 230) Restricted Cash (“ASU 2016-18”), which requires that the reconciliation of the beginning of period and end of period amounts shown in the statement of cash flows include restricted cash and restricted cash equivalents. If restricted cash is presented separately from cash and cash equivalents on the balance sheet, companies will be required to reconcile the amounts presented on the statement of cash flows to the amounts on the balance sheet. This guidance is effective for fiscal years beginning after

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December 15, 2017, and interim periods within those fiscal years. As required, the Company applied the provisions of ASU 2016-18 as of January 1, 2018. As a result, the change in restricted cash has been excluded from investing activities and included in the change in cash, cash equivalents and restricted cash and the prior year periods have been recast to reflect the new presentation.

In January 2016, the FASB issued ASU 2016-01, which supersedes the current guidance to classify equity securities with readily determinable fair values into different categories and requires equity securities to be measured at fair value with changes in the fair value recognized through net income (loss). In February 2018, the FASB issued Accounting Standards Update 2018-03, Technical Corrections and Improvements to Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, which clarifies the guidance in ASU 2016-01. The standards are effective for annual and interim periods beginning after December 15, 2017. As required, the Company applied the provisions of ASU 2016-01 as of January 1, 2018. Upon adoption, the Company recorded a cumulative effect adjustment.

In May 2014, the FASB issued Accounting Standards Update 2014-09 (“ASU 2014-09”), Revenue from Contracts with Customers (updated with Accounting Standards Update 2015-14, 2016-08, 2016-10, 2016-12 and 2016-20), which revises accounting guidance on revenue recognition that will supersede nearly all existing revenue recognition guidance under U.S. GAAP (codified as Topic 606). The core principle of this guidance is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. This guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. This guidance is effective for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years, and can be applied using a full retrospective or modified retrospective approach. The Company adopted this standard and its updates as of January 1, 2018 and elected to apply the modified retrospective transition approach. As a result, the Company is recognizing revenue on certain arrangements upon the transfer of control of product shipments rather than upon sell-through by the customer, and is recording certain costs historically in cost of sales as contra revenue.

The Company elected to apply the following practical expedients and elections in connection with the adoption of ASU 2014-09: i) taxes collected from customers and remitted to government authorities and that are related to the sales of the Company’s products, primarily in Europe, are excluded from revenues, and ii) shipping and handling activities are accounted for as fulfillment costs and are recorded in cost of sales. Payment terms related to product sales vary by jurisdiction and customer, but revenue for product sales has not been adjusted for the effects of a financing component as we expect that the period between when we transfer control of the product and when we receive payment to be one year or less.

The cumulative effect of the changes made to our consolidated January 1, 2018 balance sheet for the adoption of ASU 2014-09, ASU 2016-01 and ASU 2017-12 were as follows:

| (In millions) | Balance as of December 31, 2017 | Adjustments Due to ASU 2014-09 | Adjustments Due to ASU 2016-01 | Adjustments Due to ASU 2017-12 | Balance as of January 1, 2018 |
|---|---------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--|
| Consolidated Balance Sheet | | | | | |
| Assets | | | | | |
| Prepaid expenses and other current assets | \$ 766.1 | \$ 9.2 | \$ — | \$ — | \$ 775.3 |
| Liabilities | | | | | |
| Deferred income tax liability | 2,012.4 | 3.0 | — | — | 2,015.4 |
| Equity | | | | | |
| Retained earnings | 5,644.5 | 6.2 | 10.0 | (2.5) | 5,658.2 |

Accumulated other comprehensive loss (361.2) — (10.0) 2.5 (368.7)

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During the fourth quarter of 2018, the Company has revised the cumulative effect of the adoption of ASU 2014-09 which reduced the adjustment to beginning retained earnings by approximately \$6.6 million, net of tax. In accordance with ASU 2014-09, the disclosure of the impact of adoption on our consolidated statement of operations and balance sheet was as follows:

| (In millions) | For the Year Ended December 31, 2018 | | |
|--------------------------------------|---|--|---|
| | As Reported | Balances Without Adoption of ASC 606 | Effect of Change Increase (Decrease) |
| Consolidated Statement of Operations | | | |
| Revenues | \$11,433.9 | \$11,588.4 | \$ (154.5) |
| Cost of sales | 7,432.3 | 7,593.9 | (161.6) |
| Income tax benefit | (54.1) | (56.4) | 2.3 |
| Net earnings | 352.5 | 347.7 | 4.8 |

| (In millions) | December 31, 2018 | | |
|---|-------------------|--|---|
| | As Reported | Balances Without Adoption of ASC 606 | Effect of Change Increase (Decrease) |
| Consolidated Balance Sheet | | | |
| Prepaid expenses and other current assets | \$518.4 | \$511.3 | \$ 7.1 |
| Income taxes payable | 121.5 | 119.2 | 2.3 |
| Retained earnings | 6,010.7 | 6,005.9 | 4.8 |

3. Revenue from Contracts with Customers

Revenue Disaggregation

The following table presents the Company's net sales by therapeutic franchise for each of our reportable segments for the years ended December 31, 2018, 2017, and 2016:

| (In millions) | North America | Europe | Rest of World | Total |
|-------------------------------------|------------------|-----------|------------------|------------|
| Year Ended December 31, 2018 | | | | |
| Central Nervous System & Anesthesia | \$718.5 | \$877.5 | \$340.7 | \$1,936.7 |
| Infectious Disease | 260.8 | 441.8 | 826.4 | 1,529.0 |
| Respiratory & Allergy | 643.2 | 399.9 | 208.9 | 1,252.0 |
| Cardiovascular | 342.4 | 567.9 | 170.6 | 1,080.9 |
| Gastroenterology | 136.4 | 614.0 | 364.7 | 1,115.1 |
| Diabetes & Metabolism | 416.5 | 252.3 | 121.3 | 790.1 |
| Dermatology | 352.2 | 330.6 | 95.8 | 778.6 |
| Women's Health | 350.7 | 253.2 | 104.4 | 708.3 |
| Oncology | 543.4 | 78.4 | 137.1 | 758.9 |
| Immunology | 49.5 | 18.7 | 38.6 | 106.8 |
| Other ⁽¹⁾ | 282.0 | 323.0 | 607.3 | 1,212.3 |
| Total | \$4,095.6 | \$4,157.3 | \$3,015.8 | \$11,268.7 |

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| (In millions) | North America | Europe | Rest of World | Total |
|-------------------------------------|------------------|------------|------------------|-------------|
| Year Ended December 31, 2017 | | | | |
| Central Nervous System & Anesthesia | \$ 1,057.1 | \$ 862.7 | \$ 317.0 | \$ 2,236.8 |
| Infectious Disease | 200.0 | 343.2 | 921.7 | 1,464.9 |
| Respiratory & Allergy | 709.8 | 446.3 | 206.2 | 1,362.3 |
| Cardiovascular | 454.5 | 579.8 | 170.3 | 1,204.6 |
| Gastroenterology | 183.5 | 581.0 | 357.9 | 1,122.4 |
| Diabetes & Metabolism | 577.7 | 266.2 | 103.6 | 947.5 |
| Dermatology | 529.4 | 295.3 | 106.0 | 930.7 |
| Women's Health | 331.2 | 282.7 | 94.4 | 708.3 |
| Oncology | 487.4 | 71.2 | 148.6 | 707.2 |
| Immunology | 83.5 | 10.3 | 37.6 | 131.4 |
| Other ⁽¹⁾ | 355.5 | 219.6 | 368.8 | 943.9 |
| Total | \$ 4,969.6 | \$ 3,958.3 | \$ 2,832.1 | \$ 11,760.0 |
| (In millions) | North America | Europe | Rest of World | Total |
| Year Ended December 31, 2016 | | | | |
| Central Nervous System & Anesthesia | \$ 1,105.0 | \$ 699.5 | \$ 198.9 | \$ 2,003.4 |
| Infectious Disease | 184.0 | 270.4 | 884.0 | 1,338.4 |
| Respiratory & Allergy | 1,348.1 | 261.4 | 198.2 | 1,807.7 |
| Cardiovascular | 564.3 | 473.5 | 129.6 | 1,167.4 |
| Gastroenterology | 244.5 | 485.1 | 293.8 | 1,023.4 |
| Diabetes & Metabolism | 638.3 | 237.7 | 95.1 | 971.1 |
| Dermatology | 207.8 | 134.6 | 53.8 | 396.2 |
| Women's Health | 367.9 | 151.4 | 70.9 | 590.2 |
| Oncology | 613.6 | 53.0 | 120.1 | 786.7 |
| Immunology | 93.6 | 8.2 | 32.1 | 133.9 |
| Other ⁽¹⁾ | 262.4 | 179.0 | 307.3 | 748.7 |
| Total | \$ 5,629.5 | \$ 2,953.8 | \$ 2,383.8 | \$ 10,967.1 |

⁽¹⁾ Other consists of numerous therapeutic franchises, none of which individually exceeds 5% of consolidated net sales.

Variable Consideration

The following table presents a reconciliation of gross sales to net sales by each significant category of variable consideration during the years ended December 31, 2018, 2017 and 2016, respectively:

| (In millions) | Year Ended December 31, | | |
|--|-------------------------|---------------|---------------|
| | 2018 | 2017 | 2016 |
| Gross sales | \$ 19,588.1 | \$ 22,206.1 | \$ 21,058.9 |
| Gross to net adjustments: | | | |
| Chargebacks | (3,352.2) | (4,239.5) | (4,277.9) |
| Rebates, promotional programs and other sales allowances | (4,235.6) | (5,281.1) | (5,147.9) |
| Returns | (261.6) | (390.7) | (301.7) |
| Governmental rebate programs | (470.0) | (534.8) | (364.3) |
| Total gross to net adjustments | \$(8,319.4) | \$(10,446.1) | \$(10,091.8) |
| Net sales | \$ 11,268.7 | \$ 11,760.0 | \$ 10,967.1 |

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The following is a rollforward of the categories of variable consideration during 2018:

| (In millions) | Balance at December 31, 2017 | Current Provision Related to Sales Made in the Current Period | Checks/ Credits Issued to Third Parties | Effects of Foreign Exchange | Balance at December 31, 2018 |
|--|------------------------------------|--|---|-----------------------------------|------------------------------------|
| Chargebacks | \$ 574.3 | \$ 3,352.2 | \$(3,447.1) | \$ (1.2) | \$ 478.2 |
| Rebates, promotional programs and other sales allowances | 1,508.1 | 4,235.6 | (4,526.0) | (15.3) | 1,202.4 |
| Returns | 472.5 | 261.6 | (292.1) | (2.5) | 439.5 |
| Governmental rebate programs | 240.3 | 470.0 | (486.6) | (1.5) | 222.2 |
| Total | \$ 2,795.2 | \$ 8,319.4 | \$(8,751.8) | \$ (20.5) | \$ 2,342.3 |

Accruals for these provisions are presented in the Consolidated Financial Statements as reductions in determining net revenues and in accounts receivable and other current liabilities. Accounts receivable are presented net of allowances relating to these provisions, which were comprised of the following at December 31, 2018 and 2017, respectively:

| (In millions) | December 31, 2018 | December 31, 2017 |
|---------------------------|----------------------|----------------------|
| Accounts receivable | \$ 1,715.6 | \$ 1,977.2 |
| Other current liabilities | 626.7 | 818.0 |
| Total | \$ 2,342.3 | \$ 2,795.2 |

We have not made and do not anticipate making any significant changes to the methodologies that we use to measure provisions for variable consideration; however, the balances within these reserves can fluctuate significantly through the consistent application of our methodologies. Historically, we have not recorded in any current period any material amounts related to adjustments made to prior period reserves.

4. Acquisitions and Other Transactions

Apicore Inc.

On October 3, 2017, the Company completed the acquisition of Apicore, Inc. (“Apicore”), a U.S. based developer and manufacturer of API for approximately \$174.9 million, net of cash acquired, which includes estimated contingent consideration of approximately \$4.0 million related to the potential \$15.0 million payment contingent on the achievement of certain 2017 financial results of the acquired business. As of December 31, 2017, the contingent consideration liability was zero as Apicore did not achieve the financial results that would have triggered the contingent consideration payment.

The allocation of the \$174.9 million purchase price to the assets acquired and liabilities assumed for this business is as follows:

| (In millions) | |
|---------------------------------------|----------|
| Current assets (net of cash acquired) | \$6.5 |
| Identified intangible assets | 121.0 |
| Goodwill | 92.2 |
| Other assets | 1.9 |
| Total assets acquired | 221.6 |
| Current liabilities | (4.1) |
| Deferred tax liabilities | (40.9) |
| Other non-current liabilities | (1.7) |
| Net assets acquired | \$ 174.9 |

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The acquisition of Apicore added a diversified portfolio of API products to the Company's existing portfolio. The identified intangible assets of \$121.0 million are comprised of product rights and licenses with a weighted average useful life of seven years and includes IPR&D with a fair value of \$9.0 million at the date of the acquisition. Significant assumptions utilized in the valuation of identified intangible assets were based on company specific information and projections which are not observable in the market and are thus considered Level 3 measurements as defined by U.S. GAAP. The goodwill of \$92.2 million arising from the acquisition consisted largely of the value of the employee workforce and the expected value of products to be developed in the future. All of the goodwill was allocated to the North America segment. None of the goodwill recognized in this transaction is currently expected to be deductible for income tax purposes. The acquisition did not have a material impact on the Company's results of operations since the acquisition date or on a pro forma basis for the years ended December 31, 2017 and 2016.

Meda AB

On February 10, 2016, the Company issued an offer announcement under the Nasdaq Stockholm's Takeover Rules and the Swedish Takeover Act setting forth a public offer to the shareholders of Meda to acquire all of the outstanding shares of Meda (the "Offer"), with an enterprise value, including the net debt of Meda, of approximately Swedish krona ("SEK" or "kr") 83.6 billion (based on a SEK/USD exchange rate of 8.4158) or \$9.9 billion at announcement. On August 2, 2016, the Company announced that the Offer was accepted by Meda shareholders holding an aggregate of approximately 343 million shares, representing approximately 94% of the total number of outstanding Meda shares, as of July 29, 2016, and the Company declared the Offer unconditional. On August 5, 2016, settlement occurred with respect to the Meda shares duly tendered by July 29, 2016 and, as a result, Meda became a controlled subsidiary of the Company. Pursuant to the terms of the Offer, each Meda shareholder that duly tendered Meda shares into the Offer received at settlement (1) in respect of 80% of the number of Meda shares tendered by such shareholder, 165kr in cash per Meda share, and (2) in respect of the remaining 20% of the number of Meda shares tendered by such shareholder, 0.386 of the Company's ordinary shares per Meda share (subject to treatment of fractional shares as described in the offer document published on June 16, 2016). The non-tendered shares were required to be acquired for cash through a compulsory acquisition proceeding, in accordance with the Swedish Companies Act (Sw. aktiebolagslagen (2005:551)). The compulsory acquisition proceeding price accrued interest as required by the Swedish Companies Act. Meda's shares were delisted from the Nasdaq Stockholm exchange on August 23, 2016.

On November 1, 2016, the Company made an offer to the remaining Meda shareholders to tender all their Meda shares for cash consideration of 161.31kr per Meda share to provide such remaining shareholders with an opportunity to sell their shares in Meda to the Company in advance of the automatic acquisition of their shares for cash in connection with the compulsory acquisition proceeding. At the end of November 2016, Mylan completed the acquisition of approximately 19 million Meda shares duly tendered for aggregate cash consideration of approximately \$330.3 million. In March 2017, the Company received full legal ownership to the remaining non-tendered Meda shares in exchange for a cash payment of approximately \$71.6 million, equal to the uncontested portion of the compulsory acquisition price plus statutory interest, and the Company's arrangement of a customary bank guarantee to secure the payment of any additional cash consideration that may be awarded to the former Meda shareholders in the compulsory acquisition proceeding. In October 2017, the arbitration tribunal awarded a price of 163.07kr per Meda share, plus statutory interest of 1.5% per annum, to the former Meda shareholders subject to the compulsory acquisition proceeding. On November 15, 2017 Mylan paid an additional approximately \$0.9 million plus interest to such former Meda shareholders and, in accordance with Swedish law, the fees of the arbitrators and costs of other parties to the compulsory acquisition proceeding. The bank guarantee was released on February 27, 2018, definitively concluding the compulsory acquisition proceeding.

On August 5, 2016, the total purchase price was approximately \$6.92 billion, net of cash acquired, which includes cash consideration paid of approximately \$5.28 billion, the issuance of approximately 26.4 million Mylan N.V. ordinary shares at a fair value of approximately \$1.28 billion based on the closing price of the Company's ordinary shares on August 5, 2016, as reported by the NASDAQ Global Select Stock Market ("NASDAQ"), and an assumed liability of approximately \$431.0 million related to the compulsory acquisition proceeding of the non-tendered Meda shares. In accordance with U.S. GAAP, the Company used the acquisition method of accounting to account for this

transaction. Under the acquisition method of accounting, the assets acquired and liabilities assumed in the transaction have been recorded at their respective estimated fair values at the acquisition date. Acquisition related costs of approximately \$182 million were incurred during the year ended December 31, 2016, which were recorded as components of R&D expense, selling, general and administrative expense (“SG&A”), interest expense and other expense, net in the Consolidated Statements of Operations. These costs included approximately \$128.6 million of losses on non-designated foreign currency forward and option contracts entered into in order to economically hedge the SEK purchase price of the Offer and approximately \$45.2 million of financing fees related to the termination of a 2016 bridge credit agreement entered into in connection with the Meda acquisition.

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The allocation of the \$6.92 billion purchase price to the assets acquired and liabilities assumed for Meda is as follows:
(In millions)

| | |
|---|------------|
| Current assets (excluding inventories and net of cash acquired) | \$473.3 |
| Inventories | 468.1 |
| Property, plant and equipment | 177.5 |
| Identified intangible assets | 8,060.7 |
| Goodwill | 3,684.6 |
| Other assets | 8.8 |
| Total assets acquired | 12,873.0 |
| Current liabilities | (1,110.8) |
| Long-term debt, including current portion | (2,864.6) |
| Deferred tax liabilities | (1,613.2) |
| Pension and other postretirement benefits | (322.3) |
| Other noncurrent liabilities | (41.0) |
| Net assets acquired | \$6,921.1 |

The acquisition of Meda created a more diversified and expansive portfolio of branded and generic medicines along with a strong and growing portfolio of OTC products. The combined company has a balanced global footprint with significant scale in key geographic markets, particularly the U.S. and Europe. The acquisition of Meda also expanded our presence in key emerging markets, including, China, Russia, Turkey, and Mexico, and in countries in South East Asia, and the Middle East, which complemented Mylan's existing presence in India, Brazil and Africa (including South Africa). The Company recorded a step-up in the fair value of inventory of approximately \$107 million at the acquisition date, which was fully amortized as of December 31, 2016.

The identified intangible assets of \$8.06 billion are comprised of product rights and licenses that have a weighted average useful life of 20 years. Significant assumptions utilized in the valuation of identified intangible assets were based on company specific information and projections which are not observable in the market and are thus considered Level 3 measurements as defined by U.S. GAAP. The goodwill of \$3.68 billion arising from the acquisition consisted largely of the value of the employee workforce and the expected value of products to be developed in the future. Approximately \$3.4 billion of goodwill recognized was allocated to the Europe segment, with approximately \$290 million allocated to the North America segment, and approximately \$6 million allocated to the Rest of World segment. None of the goodwill recognized in this transaction is currently expected to be deductible for income tax purposes.

The settlement of the Offer constituted an Acceleration Event (as defined in the Rottapharm Agreement referred to below) under the Sale and Purchase Agreement, dated as of July 30, 2014 (the "Rottapharm Agreement"), among Fidim S.r.l., Meda Pharma S.p.A and Meda, the occurrence of which accelerated an unconditional deferred purchase price payment of approximately \$308 million (€275 million) relating to Meda's acquisition of Rottapharm S.p.A. which otherwise would have been payable in January 2017. The amount was paid during the year ended December 31, 2016. The operating results of Meda have been included in the Company's Consolidated Statements of Operations since the acquisition date. The total revenues of Meda for the period from the acquisition date to December 31, 2016 were \$833.9 million and the net loss, net of tax, was \$208.7 million, which includes the effects of the purchase accounting adjustments and acquisition related costs.

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Renaissance Topicals Business

On June 15, 2016, the Company completed the acquisition of the non-sterile, topicals-focused business (the “Topicals Business”) of Renaissance Acquisition Holdings, LLC (“Renaissance”) for approximately \$1.0 billion in cash at closing, including amounts deposited into escrow for potential contingent payments, subject to customary adjustments. The Topicals Business provided the Company with a complementary portfolio of commercial and pipeline products and an established U.S. sales and marketing infrastructure targeting dermatologists. The Topicals Business also provided an integrated manufacturing and development platform. In accordance with U.S. GAAP, the Company used the acquisition method of accounting to account for this transaction. Under the acquisition method of accounting, the assets acquired and liabilities assumed in the transaction were recorded at their respective estimated fair values at the acquisition date. The U.S. GAAP purchase price was \$972.7 million, which includes estimated contingent consideration of approximately \$16 million related to the potential \$50 million payment contingent on the achievement of certain 2016 financial targets. The contingent consideration was resolved in the fourth quarter of 2017 for a net payment of approximately \$40 million and the Company recognized a charge of \$23.5 million included as a component of litigation settlements and other contingencies, net in the Company’s Consolidated Statements of Operations for the year ended December 31, 2017.

The allocation of the \$972.7 million purchase price to the assets acquired and liabilities assumed for the Topicals Business is as follows:

(In millions)

| | |
|--|----------|
| Current assets (excluding inventories) | \$57.7 |
| Inventories | 74.2 |
| Property, plant and equipment | 54.8 |
| Identified intangible assets | 467.0 |
| In-process research and development | 275.0 |
| Goodwill | 318.6 |
| Other assets | 0.1 |
| Total assets acquired | 1,247.4 |
| Current liabilities | (74.2) |
| Deferred tax liabilities | (194.6) |
| Other noncurrent liabilities | (5.9) |
| Net assets acquired | \$972.7 |

The acquisition of the Topicals Business broadened the Company’s dermatological portfolio. The amount allocated to IPR&D represents an estimate of the fair value of purchased in-process technology for research projects that, as of the closing date of the acquisition, had not reached technological feasibility and had no alternative future use. The fair value of IPR&D of \$275.0 million was based on the excess earnings method, which utilizes forecasts of expected cash inflows (including estimates for ongoing costs) and other contributory charges. A discount rate of 12.5% was utilized to discount net cash inflows to present values. IPR&D is accounted for as an indefinite-lived intangible asset and will be subject to impairment testing until completion or abandonment of the projects. Upon successful completion and launch of each product, the Company will make a determination of the estimated useful life of the individual IPR&D asset and amounts will be allocated to product rights and licenses in intangible assets. The acquired IPR&D projects are in various stages of completion and the estimated costs to complete these projects total approximately \$15 million, which is expected to be incurred through 2022. There are risks and uncertainties associated with the timely and successful completion of the projects included in IPR&D, and no assurances can be given that the underlying assumptions used to estimate the fair value of IPR&D will not change or the timely completion of each project to commercial success will occur.

The identified intangible assets of \$467.0 million are comprised of \$454.0 million of product rights and licenses that have a weighted average useful life of 14 years and \$13.0 million of contract manufacturing agreements that have a weighted average useful life of five years. Significant assumptions utilized in the valuation of identified intangible assets were based on company specific information and projections which are not observable in the market and are

thus considered Level 3 measurements as defined by U.S. GAAP.

The goodwill of \$318.6 million arising from the acquisition consisted largely of the value of the employee workforce and the expected value of products to be developed in the future. All of the goodwill was assigned to the North America

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segment. None of the goodwill recognized in this transaction is currently expected to be deductible for income tax purposes. Acquisition related costs of approximately \$3.6 million were incurred during the year ended December 31, 2016 related to this transaction, which were recorded as a component of SG&A in the Consolidated Statements of Operations. The acquisition did not have a material impact on the Company's results of operations since the acquisition date or on a pro forma basis for the year ended December 31, 2016.

Unaudited Pro Forma Financial Results

The following table presents supplemental unaudited pro forma information for the acquisition of Meda as if it had occurred on January 1, 2015. The unaudited pro forma results reflect certain adjustments related to past operating performance and acquisition accounting adjustments, such as increased amortization expense based on the fair value of assets acquired, the impact of transaction costs and the related income tax effects. The unaudited pro forma results do not include any anticipated synergies which may be achievable subsequent to acquisition of Meda. Accordingly, the unaudited pro forma results are not necessarily indicative of the results that actually would have occurred, nor are they indicative of the future operating results of Mylan N.V.

| | Year Ended December 31, 2016 |
|--|---------------------------------------|
| (Unaudited, in millions, except per share amounts) | |
| Total revenues | \$ 12,376.0 |
| Net earnings | \$ 560.6 |
| Earnings per ordinary share: | |
| Basic | \$ 1.06 |
| Diluted | \$ 1.05 |
| Weighted average ordinary shares outstanding: | |
| Basic | 528.7 |
| Diluted | 536.2 |

Other Transactions

On December 1, 2018, the Company and certain subsidiaries of Aspen Pharmacare Holdings Limited entered into an agreement for Mylan to distribute a portfolio of prescription and OTC products in Australia and New Zealand. The agreement includes an option for Mylan to purchase the rights to the portfolio for approximately \$135 million.

On August 31, 2018, the Company completed an agreement with certain subsidiaries of Novartis AG ("Novartis") to purchase the worldwide rights to their global cystic fibrosis products consisting of the TOBI Podhaler® and TOBI® solution. Tobramycin is the standard of care for treatment of pseudomonas aeruginosa, a leading driver of infection in cystic fibrosis. These products further strengthen our existing presence in cystic fibrosis, especially with our Creon Franchise in Europe, Australia, Japan and Canada. The asset acquisition allows us to further extend our respiratory franchise into rare/orphan disease indications and broaden our portfolio into dry powdered inhalers and nebulized products. Tobi Podhaler™ is manufactured using a proprietary Pulmosphere technology for which we have acquired exclusive rights for use, hence we expect a high barrier for generic entry.

Under the terms of the agreement, Novartis is owed fixed consideration of \$463.0 million which consists of \$240.0 million which was paid at closing and deferred payments of \$130.0 million included in other current liabilities and \$93.0 million included in other long-term obligations, due in 2019 and 2020, respectively. Novartis is also eligible to receive a contingent payment of up to \$20 million. The Company also entered into a supply agreement with Novartis to purchase the products for up to three years from the date of closing. The Company has recorded a liability of approximately \$91 million related to supply obligations.

The Company accounted for this transaction as an asset acquisition and recognized an intangible asset for the product rights of \$574.8 million. The intangible asset is being amortized over a useful life of 10 years.

On February 28, 2018, the Company and Revance Therapeutics, Inc. ("Revance") entered into a collaboration agreement (the "Revance Collaboration Agreement") pursuant to which the Company and Revance will collaborate exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize a biosimilar to the branded biologic

product (onabotulinumtoxinA) marketed as BOTOX®.

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Under the Revance Collaboration Agreement, the Company will be primarily responsible for (a) clinical development activities outside of North America (excluding Japan) (the “ex-U.S. Mylan territories”), (b) regulatory activities, and (c) commercialization for any approved product. Revance will be primarily responsible for (a) non-clinical development activities, (b) clinical development activities in North America, and (c) manufacturing and supply of clinical drug substance and drug product; Revance will be solely responsible for an initial portion of non-clinical development costs. The remaining portion of any non-clinical development costs and clinical development costs for obtaining approval in the U.S. and Europe will be shared equally between the parties, and the Company will be responsible for all other clinical development costs and commercialization expenses. Upon closing, Revance received a non-refundable upfront payment of \$25.0 million. In addition, under the Revance Collaboration Agreement, Revance can receive potential development milestone payments of up to \$100.0 million, in the aggregate, upon the achievement of specified clinical and regulatory milestones and potential tiered sales milestones of up to \$225.0 million. In addition, Mylan will pay Revance royalties on sales of the biosimilar in the ex-U.S. Mylan territories. The Company accounted for this transaction as an asset acquisition of IPR&D and the total upfront payment was expensed as a component of R&D expense during the year ended December 31, 2018.

During the year ended December 31, 2018, the Company completed four agreements to acquire certain intellectual property rights and marketing authorizations for products that were in the development stage, including agreements with Fujifilm Kyowa Kirin Biologics Co., Ltd. (“FKB”), Mapi Pharma Ltd., and Lupin Limited. The Company also completed the acquisition of intellectual property rights and marketing authorizations related to a commercialized product in certain rest of world markets for \$220.0 million, of which \$160.0 million was paid at closing and \$20 million was paid in the fourth quarter of 2018, with the remaining amount due in 2019 and included in other current liabilities. The Company is accounting for these transactions as asset acquisitions and a useful life of five years is being used to amortize the asset related to the commercialized product. The Company recorded expense of approximately \$53.7 million as a component of R&D expense related to non-refundable upfront payments for agreements for products in development during the year ended December 31, 2018. Certain of the agreements include additional development and commercial milestones.

As part of the Meda acquisition, the Company acquired the in-licensed rights to Betadine in certain European markets. These rights were set to expire on December 31, 2017. Under the licensing agreement, Meda had a binding option to acquire a perpetual license for the rights to Betadine under certain conditions. In October 2017, the Company finalized an agreement to acquire the perpetual license. An estimated liability of approximately \$300 million for the purchase of these rights was accrued for on the Meda acquisition opening balance sheet. On January 2, 2018, the Company paid the amounts due to acquire the perpetual license.

On December 25, 2017, the Company entered into an agreement to reacquire certain intellectual property rights and marketing authorizations related to a product commercialized in Japan for \$90.0 million, which was paid in 2018. The Company accounted for this transaction as an asset acquisition and the asset is being amortized over a useful life of five years.

On November 30, 2017, the Company entered into an exclusive license and supply agreement with Natco Pharma Limited for API related to the Company’s Glatiramer Acetate Injection 40 mg/mL product for \$22.5 million paid at closing and \$29.5 million due through 2020. The license grants the Company the exclusive right to license, market and sell the product in North America and certain other territories. The intangible asset recognized totaled \$52 million and was amortized over a useful life of 15 months.

On September 29, 2017, the Company completed the acquisition of intellectual property rights and marketing authorizations related to a product in certain markets for \$40 million. The Company accounted for this transaction as an asset acquisition and the asset is being amortized over a useful life of five years.

On June 19, 2017, the Company completed the acquisition of a portfolio of four generic pharmaceutical products in the U.S. The acquisition price was \$256.7 million and the Company accounted for this transaction as an asset acquisition. The intangible asset recognized totaled \$252.5 million with the remaining assets primarily consisting of receivables. The intangible asset was being amortized over a useful life of seven years through December 31, 2018. Subsequently, the Company has revised the remaining useful life to four years.

On June 2, 2017, the Company completed the acquisition of additional intellectual property rights and marketing authorizations in certain rest of world markets for a product that the Company previously licensed in certain European markets. The acquisition price was \$128.0 million and the Company accounted for this transaction as an asset acquisition. The intangible asset is being amortized over a useful life of five years.

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On March 29, 2017, the Company announced that it had completed its acquisition of the global rights to the Cold-EEZE® brand cold remedy line from ProPhase Labs, Inc. for approximately \$50 million in cash. The Company accounted for this transaction as an asset acquisition and the asset is being amortized over a useful life of 15 years. On February 14, 2017, the Company entered into a joint development and marketing agreement for a respiratory product that resulted in approximately \$50 million in R&D expense during the year ended December 31, 2017. During the year ended December 31, 2016, the Company entered into an agreement to acquire a marketed pharmaceutical product for an upfront payment of approximately \$57.9 million in cash. The Company accounted for this transaction as an asset acquisition and is amortizing the product over a weighted useful life of five years.

5. Balance Sheet Components

Selected balance sheet components consist of the following:

Cash and restricted cash

| (In millions) | December 31, December 31, | |
|--|---------------------------|----------|
| | 2018 | 2017 |
| Cash and cash equivalents | \$ 388.1 | \$ 292.1 |
| Restricted cash, included in prepaid expenses and other current assets | 1.2 | 77.8 |
| Cash, cash equivalents and restricted cash | \$ 389.3 | \$ 369.9 |

Accounts receivable, net

| (In millions) | December 31, December 31, | |
|--------------------------|---------------------------|------------|
| | 2018 | 2017 |
| Trade receivables, net | \$ 2,416.5 | \$ 3,173.1 |
| Other receivables | 464.5 | 439.3 |
| Accounts receivable, net | \$ 2,881.0 | \$ 3,612.4 |

Total allowances for doubtful accounts were \$98.2 million and \$75.3 million at December 31, 2018 and 2017, respectively. Mylan performs ongoing credit evaluations of its customers and generally does not require collateral. Approximately 21% and 35% of the accounts receivable balances represent amounts due from three customers at December 31, 2018 and 2017, respectively.

Inventories

| (In millions) | December 31, December 31, | |
|-----------------|---------------------------|------------|
| | 2018 | 2017 |
| Raw materials | \$ 955.7 | \$ 895.5 |
| Work in process | 369.9 | 384.7 |
| Finished goods | 1,254.6 | 1,262.5 |
| Inventories | \$ 2,580.2 | \$ 2,542.7 |

Inventory reserves totaled \$228.2 million and \$171.0 million at December 31, 2018 and 2017, respectively. Included as a component of cost of sales is expense related to the net realizable value of inventories of \$300.5 million, \$229.3 million and \$195.7 million for the years ended December 31, 2018, 2017 and 2016, respectively.

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Prepaid expenses and other current assets

| (In millions) | December 31, 2018 | December 31, 2017 |
|--|----------------------|----------------------|
| Prepaid expenses | \$ 130.6 | \$ 119.8 |
| Restricted cash | 1.2 | 77.8 |
| Available-for-sale fixed income securities | 25.0 | 31.5 |
| Fair value of financial instruments | 33.8 | 88.9 |
| Equity securities | 32.5 | 79.1 |
| Other current assets | 295.3 | 369.0 |
| Prepaid expenses and other current assets | \$ 518.4 | \$ 766.1 |

Prepaid expenses consists primarily of prepaid rent, insurance and other individually insignificant items. At December 31, 2017, restricted cash principally related to amounts deposited in escrow for contingent consideration payments related to the Company's acquisition of Agila Specialties Private Limited ("Agila"). During the year ended December 31, 2018, approximately \$51.0 million of restricted cash was remitted to Strides Arcolab Limited ("Strides Arcolab") as part of the final settlement of the Agila contingent consideration and \$23.5 million to Merck KGaA for the remittance of certain income tax refunds.

Property, plant and equipment, net

| (In millions) | December 31, 2018 | December 31, 2017 |
|-------------------------------------|----------------------|----------------------|
| Machinery and equipment | \$ 2,421.2 | \$ 2,414.5 |
| Buildings and improvements | 1,182.3 | 1,191.7 |
| Construction in progress | 239.7 | 252.9 |
| Land and improvements | 131.3 | 143.1 |
| Gross property, plant and equipment | 3,974.5 | 4,002.2 |
| Accumulated depreciation | 1,804.3 | 1,663.1 |
| Property, plant and equipment, net | \$ 2,170.2 | \$ 2,339.1 |

Capitalized software costs included on our Consolidated Balance Sheets were \$112.0 million and \$143.0 million, net of accumulated depreciation, at December 31, 2018 and 2017, respectively. The Company periodically reviews the estimated useful lives of assets and makes adjustments when appropriate. Depreciation expense was approximately \$279.5 million, \$287.6 million and \$259.4 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Other assets

| (In millions) | December 31, 2018 | December 31, 2017 |
|---|----------------------|----------------------|
| Equity method investments, clean energy investments | \$ 138.7 | \$ 226.0 |
| Other long-term assets | 73.7 | 79.6 |
| Other assets | \$ 212.4 | \$ 305.6 |

Accounts payable

| (In millions) | December 31, 2018 | December 31, 2017 |
|------------------------|----------------------|----------------------|
| Trade accounts payable | \$ 1,123.2 | \$ 976.0 |
| Other payables | 493.8 | 476.5 |
| Accounts payable | \$ 1,617.0 | \$ 1,452.5 |

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Other current liabilities

| (In millions) | December 31, 2018 | December 31, 2017 |
|--|----------------------|----------------------|
| Accrued sales allowances | \$ 626.7 | \$ 818.0 |
| Payroll and employee benefit liabilities | 399.7 | 404.6 |
| Legal and professional accruals, including litigation accruals | 128.1 | 241.1 |
| Contingent consideration | 158.3 | 167.8 |
| Restructuring | 62.3 | 91.5 |
| Equity method investments, clean energy investments | 45.1 | 56.7 |
| Accrued interest | 62.4 | 42.3 |
| Fair value of financial instruments | 29.4 | 31.1 |
| Other | 635.6 | 1,111.4 |
| Other current liabilities | \$ 2,147.6 | \$ 2,964.5 |

In the fourth quarter of 2018, the Company announced the voluntary recall of valsartan and certain combination valsartan medicines in various countries due to the detection of trace amounts of an impurity, N-nitrosodiethylamine (“NDEA”) contained in the API valsartan, USP, manufactured by Mylan India. The impact of this recall on the Company’s consolidated financial statements for the year ended December 31, 2018 was approximately \$22.6 million, primarily related to recall costs and inventory reserves. Depending on the scope of regulatory actions, and severity of the impurity, the Company may face additional loss of revenues and profits and incur contractual or other litigation costs. There can be no assurance that future costs related to the recall will not exceed amounts recorded.

Other long-term obligations

| (In millions) | December 31, 2018 | December 31, 2017 |
|---|----------------------|----------------------|
| Employee benefit liabilities | \$ 397.7 | \$ 408.2 |
| Equity method investments, clean energy investments | 100.3 | 171.8 |
| Contingent consideration | 197.0 | 285.9 |
| Tax contingencies | 162.1 | 237.7 |
| Other | 239.7 | 132.1 |
| Other long-term obligations | \$ 1,096.8 | \$ 1,235.7 |

6. Equity Method Investments

The Company has three equity method investments in limited liability companies that own refined coal production plants (the “clean energy investments”), whose activities qualify for income tax credits under Section 45 of the U.S. Internal Revenue Code of 1986, as amended (the “Code”). The Company does not consolidate these entities as we have determined that we are not the primary beneficiary of these entities and do not have the power to individually direct the activities of these entities. Accordingly, these investments are accounted for under the equity method of accounting. For each of the clean energy investments, the Company has entered into notes payable with the respective project sponsor, which in part will be paid to the sponsor as certain production levels are met.

During 2018, the Company and a project sponsor agreed to terminate two previous investments. Under the termination agreements, the Company returned its ownership interest in the projects to the sponsor and in exchange the Company will have no further obligations with respect to the notes payable for these projects.

Also, during 2018, the Company entered into amended agreements related to the three remaining investments. These amendments effectively reduce the amount of expected future variable debt payments to the respective project sponsor.

During the year ended December 31, 2017 as a result of a decline in the current and expected future production levels at certain of the facilities, the Company impaired its investment balance and other assets by approximately \$47.0 million and reduced the related long-term obligations for these investments by approximately \$89.0 million resulting in a net gain of \$42.0 million which was recognized as a component of other expense, net in the Consolidated Statement of Operations.

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The carrying values and respective balance sheet locations of the Company's clean energy investments were as follows at December 31, 2018 and 2017, respectively:

| (In millions) | December 31, December 31, | |
|---|---------------------------|----------|
| | 2018 | 2017 |
| Other assets | \$ 138.7 | \$ 226.0 |
| Total liabilities | 145.4 | 228.5 |
| Included in other current liabilities | 45.1 | 56.7 |
| Included in other long-term obligations | 100.3 | 171.8 |

Summarized financial information, in the aggregate, of the Company's equity method investments on a 100% basis as of December 31, 2018 and 2017 and for the years ended December 31, 2018, 2017 and 2016 are as follows:

| (In millions) | December 31, December 31, | | |
|-------------------------------------|---------------------------|-----------|-------------------------|
| | 2018 | 2017 | |
| Current assets | \$ 36.6 | \$ 56.4 | |
| Noncurrent assets | 2.3 | 18.2 | |
| Total assets | 38.9 | 74.6 | |
| Current liabilities | 32.8 | 56.1 | |
| Noncurrent liabilities | 1.7 | 3.6 | |
| Total liabilities | 34.5 | 59.7 | |
| Net assets | \$ 4.4 | \$ 14.9 | |
| | | | Year Ended December 31, |
| (In millions) | 2018 | 2017 | 2016 |
| Total revenues | \$483.3 | \$473.0 | \$589.4 |
| Gross (loss) profit | (21.1) | (12.8) | (13.2) |
| Operating and non-operating expense | 21.9 | 22.3 | 22.2 |
| Net loss | \$(43.0) | \$(35.1) | \$(35.4) |

The Company's net losses from equity method investments include amortization expense related to the excess of the cost basis of the Company's investment to the underlying assets of each individual investee. For the years ended December 31, 2018, 2017 and 2016, the Company's share of the net loss of the equity method investments was \$78.7 million, \$58.0 million, and \$112.8 million, respectively, which was recognized as a component of other expense, net in the Consolidated Statements of Operations. The Company recognizes the income tax credits and benefits from the clean energy investments as part of its provision for income taxes.

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7. Goodwill and Other Intangible Assets

The changes in the carrying amount of goodwill for the years ended December 31, 2018 and 2017 are as follows:

| (In millions) | North America Segment | Europe Segment | Rest of World Segment | Total |
|----------------------------------|-----------------------------|-------------------|-----------------------------|-----------|
| Balance at December 31, 2016: | | | | |
| Goodwill | \$3,990.4 | \$3,859.1 | \$1,767.4 | \$9,616.9 |
| Accumulated impairment losses | (385.0) | — | — | (385.0) |
| | 3,605.4 | 3,859.1 | 1,767.4 | 9,231.9 |
| Acquisitions | 92.2 | — | — | 92.2 |
| Reclassifications ⁽¹⁾ | (200.1) | 382.2 | (182.1) | — |
| Measurement period adjustments | — | 7.7 | — | 7.7 |
| Divestiture | — | (1.3) | — | (1.3) |
| Foreign currency translation | 52.1 | 719.4 | 103.7 | 875.2 |
| | 3,549.6 | 4,967.1 | 1,689.0 | 10,205.7 |
| Balance at December 31, 2017: | | | | |
| Goodwill | 3,934.6 | 4,967.1 | 1,689.0 | 10,590.7 |
| Accumulated impairment losses | (385.0) | — | — | (385.0) |
| | 3,549.6 | 4,967.1 | 1,689.0 | 10,205.7 |
| Foreign currency translation | (41.7) | (309.7) | (106.5) | (457.9) |
| | 3,507.9 | 4,657.4 | 1,582.5 | 9,747.8 |
| Balance at December 31, 2018 | | | | |
| Goodwill | 3,892.9 | 4,657.4 | 1,582.5 | 10,132.8 |
| Accumulated impairment losses | (385.0) | — | — | (385.0) |
| | \$3,507.9 | \$4,657.4 | \$1,582.5 | \$9,747.8 |

⁽¹⁾ The reclassifications relate to the allocation of goodwill for the Meda acquisition.

Intangible assets consist of the following components at December 31, 2018 and 2017:

| (In millions) | Weighted Average Life (Years) | Cost | Accumulated Amortization | Net Book Value |
|---|-------------------------------|------------|-----------------------------|-------------------|
| December 31, 2018 | | | | |
| Product rights, licenses and other ⁽¹⁾ | 15 | \$20,264.1 | \$ 7,225.1 | \$13,039.0 |
| In-process research and development | | 625.6 | — | 625.6 |
| | | \$20,889.7 | \$ 7,225.1 | \$13,664.6 |
| December 31, 2017 | | | | |
| Product rights, licenses and other ⁽¹⁾ | 15 | \$20,338.7 | \$ 5,906.1 | \$14,432.6 |
| In-process research and development | | 813.2 | — | 813.2 |
| | | \$21,151.9 | \$ 5,906.1 | \$15,245.8 |

⁽¹⁾ Represents amortizable intangible assets. Other intangibles consist principally of customer lists and contractual rights.

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Product rights and licenses are primarily comprised of the products marketed at the time of acquisition. These product rights and licenses relate to numerous individual products, the net book value of which, by therapeutic franchise, is as follows:

| (In millions) | December 31, December 31, | |
|---------------------------------------|---------------------------|-------------|
| | 2018 | 2017 |
| Central Nervous System and Anesthesia | \$ 2,148.9 | \$ 2,453.7 |
| Dermatology | 2,125.7 | 2,393.0 |
| Gastroenterology | 1,790.9 | 2,050.0 |
| Diabetes and Metabolism | 1,232.4 | 1,425.6 |
| Cardiovascular | 1,541.9 | 1,779.5 |
| Respiratory and Allergy | 2,084.1 | 1,769.5 |
| Infectious Disease | 596.0 | 494.8 |
| Oncology | 206.0 | 380.1 |
| Women's Healthcare | 315.1 | 371.4 |
| Immunology | 258.8 | 301.5 |
| Other ⁽¹⁾ | 694.9 | 970.1 |
| | \$ 12,994.7 | \$ 14,389.2 |

(1) Other consists of numerous therapeutic classes, none of which individually exceeds 5% of total product rights and licenses.

Amortization expense and intangible asset impairment charges, which are included as a component of amortization expense, which is classified primarily within cost of sales in the Consolidated Statements of Operations, for the years ended December 31, 2018, 2017 and 2016 was as follows:

| (In millions) | Year ended December 31, | | |
|--|-------------------------|-----------|-----------|
| | 2018 | 2017 | 2016 |
| Intangible asset amortization expense | \$1,606.4 | \$1,437.4 | \$1,195.3 |
| IPR&D intangible asset impairment charges | 117.7 | 74.6 | 49.9 |
| Finite-lived intangible asset impairment charges | 106.3 | 6.2 | 18.4 |
| Total intangible asset amortization expense (including impairment charges) | \$1,830.4 | \$1,518.2 | \$1,263.6 |

The assessment for impairment of finite-lived intangibles is based on our ability to recover the carrying value of the long-lived assets or asset grouping by analyzing the expected future undiscounted pre-tax cash flows specific to the asset or asset grouping. If the carrying amount is greater than the undiscounted cash flows, the Company recognizes an impairment loss for the excess of book value over fair value based on the discounted cash flows.

Significant management judgment is involved in estimating the recoverability of these assets and is dependent upon the accuracy of the assumptions used in making these estimates, as well as how the estimates compare to the eventual future operating performance of the specific asset or asset grouping. The fair value of finite-lived intangible assets was calculated as the present value of the estimated future net cash flows using a market rate of return. The assumptions inherent in the estimated future cash flows include, among other things, the impact of the current competitive environment and future market expectations. Discount rates ranging between 9.0% and 10.0% were utilized in the valuations performed during the years ended December 31, 2018, 2017 and 2016. At December 31, 2018 and 2017, the Company's finite-lived intangible assets totaled \$13.04 billion and \$14.43 billion, respectively. Any future long-lived assets impairment charges could have a material impact on the Company's consolidated financial condition and results of operations.

The Company's IPR&D assets are tested at least annually for impairment, but they may be tested whenever certain impairment indicators are present. Impairment is determined to exist when the fair value of IPR&D assets, which was based upon updated forecasts and commercial development plans, is less than the carrying value of the assets being tested. The fair value of IPR&D was calculated as the present value of the estimated future net cash flows using a market rate of return. The assumptions inherent in the estimated future cash flows include, among other things, the

impact of changes to the development programs, the projected development and regulatory time frames and the current competitive environment. Discount rates

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ranging between 9.5% and 13.0%, 8.4% and 10.5%, and 8.5% and 11.9% were utilized in the valuations performed during the years ended December 31, 2018, 2017 and 2016 respectively.

The fair value of both IPR&D and finite-lived intangible assets was determined based upon detailed valuations employing the income approach which utilized Level 3 inputs, as defined in Note 8 Financial Instruments and Risk Management. Changes to any of the Company's assumptions including changes to or abandonment of development programs, regulatory timelines, discount rates or the competitive environment related to the assets could lead to future material impairment charges.

In December 2011, the Company completed the acquisition of the exclusive worldwide rights to develop, manufacture and commercialize a generic equivalent to GlaxoSmithKline's Advair® Diskus and Seretide® Diskus incorporating Pfizer Inc.'s ("Pfizer") proprietary dry powder inhaler delivery platform (the "respiratory delivery platform"). The Company accounted for this transaction as a purchase of a business and utilized the acquisition method of accounting. As of December 31, 2018, the Company has an IPR&D asset of \$347.2 million and related contingent consideration liability of \$336.5 million. The Company performed an analysis and valuation of the IPR&D asset and the fair value of the related contingent consideration liability using a discounted cash flow model. The model contained certain key assumptions including: the expected product launch date, the number of competitors, the timing of competition and a discount factor based on an industry specific weighted average cost of capital. Based on the analysis performed, the Company determined that the fair value of the IPR&D asset was substantially in excess of its carrying value, and the asset was not impaired at December 31, 2018. Additionally, a fair value adjustment was required for the related contingent consideration liability resulting in a gain of approximately \$44.0 million for the year ended December 31, 2018 based upon changes to assumptions relating to the timing of the product launch along with other competitive and market factors. The fair value of the contingent consideration liability was determined based upon detailed valuations employing the income approach which utilized Level 3 inputs, as defined in Note 8 - Financial Instruments and Risk Management. On January 30, 2019, the Company received FDA approval of Wixela™ Inhub™ (fluticasone propionate and salmeterol inhalation powder, USP), the first generic of GlaxoSmithKline's Advair Diskus®. The commercial launch of the Wixela™ Inhub™ occurred in February 2019. The Company expects to reclassify the IPR&D asset of \$347.2 million to product rights and licenses in the first quarter of 2019. Market conditions and other factors may result in significant future changes in the projections and assumptions utilized in the discounted cash flow model, which could lead to material adjustments to the amounts recorded for intangible assets and contingent consideration.

The Company has performed its annual goodwill impairment test as of April 1, 2018 on a quantitative basis for its four reporting units, North America Generics, North America Brands, Europe and Rest of World. In estimating each reporting unit's fair value, the Company performed an extensive valuation analysis, utilizing both income and market-based approaches, except for the North America Brands reporting unit where the fair value was estimated utilizing the income approach. The determination of the fair value of the reporting units requires the Company to make significant estimates and assumptions that affect the reporting unit's expected future cash flows. These estimates and assumptions, utilizing Level 3 inputs, primarily include, but are not limited to, market multiples, control premiums, the discount rate, terminal growth rates, operating income before depreciation and amortization, and capital expenditures forecasts. Due to the inherent uncertainty involved in making these estimates, actual results could differ from those estimates. In addition, changes in underlying assumptions, especially as it relates to the key assumptions detailed, could have a significant impact on the fair value of the reporting units.

As of the date of our annual impairment test, the allocation of the Company's total goodwill was as follows: North America Generics \$2.89 billion, North America Brands \$0.66 billion, Europe \$4.97 billion and Rest of World \$1.80 billion. The fair value of the North America Generics, North America Brands and Rest of World reporting units was substantially in excess of the respective unit's carrying value. For the Europe reporting unit, the estimated fair value exceeded its carrying value by approximately \$800.0 million or 6.0%. The excess fair value for the Europe reporting unit is consistent with the result of the Company's 2017 annual impairment test. As it relates to the income approach for the Europe reporting unit at April 1, 2018, the Company forecasted cash flows for the next 5 years. During the forecast period, the revenue compound annual growth rate was approximately 3.5%. A terminal value year was

calculated with a 2.0% revenue growth rate applied. The discount rate utilized was 9.0% and the estimated tax rate was 24.0%. Under the market-based approach, we utilized an estimated range of market multiples of 9.0 to 10.5 times EBITDA plus a control premium of 15.0%. If all other assumptions are held constant, a reduction in the terminal value growth rate by 2.0% or an increase in discount rate by 1.5% would result in an impairment charge for the Europe reporting unit.

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Intangible asset amortization expense for the years ended December 31, 2019 through 2023 is estimated to be as follows:

(In millions)

| | |
|------|----------|
| 2019 | \$ 1,703 |
| 2020 | 1,544 |
| 2021 | 1,462 |
| 2022 | 1,392 |
| 2023 | 967 |

8. Financial Instruments and Risk Management

The Company is exposed to certain financial risks relating to its ongoing business operations. The primary financial risks that are managed by using derivative instruments are foreign currency risk and interest rate risk.

Foreign Currency Risk Management

In order to manage certain foreign currency risks, the Company enters into foreign exchange forward contracts to mitigate risk associated with changes in spot exchange rates of mainly non-functional currency denominated assets or liabilities. The foreign exchange forward contracts are measured at fair value and reported as current assets or current liabilities on the Consolidated Balance Sheets. Any gains or losses on the foreign exchange forward contracts are recognized in earnings in the period incurred in the Consolidated Statements of Operations.

The Company has also entered into forward contracts to hedge forecasted foreign currency denominated sales from certain international subsidiaries. These contracts are designated as cash flow hedges to manage foreign currency transaction risk and are measured at fair value and reported as current assets or current liabilities on the Consolidated Balance Sheets. Any changes in the fair value of designated cash flow hedges are deferred in accumulated other comprehensive earnings (“AOCE”) and are reclassified into earnings when the hedged item impacts earnings.

Net Investment Hedges

The Company may hedge the foreign currency risk associated with certain net investment positions in foreign subsidiaries by either borrowing directly in foreign currencies and designating all or a portion of the foreign currency debt as a hedge of the applicable net investment position or entering into foreign currency swaps that are designated as hedges of net investments.

The Company designated certain Euro borrowings as a hedge of its investment in certain Euro-functional currency subsidiaries in order to manage foreign currency translation risk. Borrowings designated as net investment hedges are marked-to-market using the current spot exchange rate as of the end of the period, with gains and losses included in the foreign currency translation component of AOCE until the sale or substantial liquidation of the underlying net investments. In addition, the Company manages the related foreign exchange risk of the Euro borrowings not designated as net investment hedges through certain Euro denominated financial assets and forward currency swaps. The following table summarizes the principal amounts of the Company’s outstanding Euro borrowings and the notional amounts of the Euro borrowings designated as net investment hedges:

| (in millions) | Principal Amount | Notional Amount Designated as a Net Investment Hedge | |
|-----------------------------------|------------------|--|----------------------|
| | | December 31, 2018 | December 31, 2017 |
| 2.250% Euro Senior Notes due 2024 | €1,000.0 | €1,000.0 | €1,000.0 |
| 3.125% Euro Senior Notes due 2028 | 750.0 | 750.0 | 750.0 |
| 1.250% Euro Senior Notes due 2020 | 750.0 | 104.0 | 104.0 |
| 2.125% Euro Senior Notes due 2025 | 500.0 | 500.0 | — |
| Floating Rate Euro Notes due 2020 | 500.0 | — | — |
| Total | €6,500.0 | €2,354.0 | €1,854.0 |

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Interest Rate Risk Management

The Company enters into interest rate swaps in order to manage interest rate risk associated with the Company's fixed-rate and floating-rate debt. Interest rate swaps that meet specific accounting criteria are accounted for as fair value or cash flow hedges. All derivative instruments used to manage interest rate risk are measured at fair value and reported as current assets or current liabilities in the Consolidated Balance Sheets. For fair value hedges, the changes in the fair value of both the hedging instrument and the underlying debt obligations are included in interest expense. For cash flow hedges, the change in fair value of the hedging instrument is deferred through AOCE and is reclassified into earnings when the hedged item impacts earnings.

Cash Flow Hedging Relationships

The Company's interest rate swaps designated as cash flow hedges fix the interest rate on a portion of the Company's variable-rate debt or hedge part of the Company's interest rate exposure associated with the variability in the future cash flows attributable to changes in interest rates. Any changes in fair value are included in earnings or deferred through AOCE, depending on the nature and effectiveness of the offset. Any ineffectiveness in a cash flow hedging relationship is recognized immediately in earnings in the Consolidated Statements of Operations.

Following the acquisition of Meda, the Company designated certain interest rate swaps with a notional amount of €750 million as cash flow hedges. In the fourth quarter of 2016, the Company repaid the related debt instrument and terminated these swaps.

In anticipation of issuing fixed-rate debt, the Company may use treasury rate locks or forward starting interest rate swaps that are designated as cash flow hedges. In September 2015, the Company entered into a series of forward starting swaps to hedge against changes in interest rates related to future debt issuances. These swaps were designated as cash flow hedges of expected future issuances of long-term bonds. The Company executed \$500 million of notional value swaps with an effective date of June 2016 and an additional \$500 million of notional value swaps with an effective date of November 2016. Both sets of swaps had a maturity of ten years. During the second quarter of 2016, the Company issued \$2.25 billion in an aggregate principal amount of 3.950% Senior Notes due 2026 (the "2026 Senior Notes") and the Company terminated these swaps. As a result of this termination, the Company recorded losses of \$64.9 million in AOCE, which are being amortized over the life of the 2026 Senior Notes.

Fair Value Hedging Relationships

The Company's interest rate swaps designated as fair value hedges convert the fixed rate on a portion of the Company's fixed-rate senior notes to a variable rate. Any changes in the fair value of these derivative instruments, as well as the offsetting change in fair value of the portion of the fixed-rate debt being hedged, is included in interest expense. In December 2013, the Company entered into interest rate swaps with a notional value of \$750 million that were designated as hedges of the Company's 3.125% Senior Notes due 2023. The variable rate was 2.86% at December 31, 2018. The total notional amount of the Company's interest rate swaps on fixed-rate debt was \$750 million as of December 31, 2018 and 2017.

Credit Risk Management

The Company regularly reviews the creditworthiness of its financial counterparties and does not expect to incur a significant loss from the failure of any counterparties to perform under any agreements. The Company is not subject to any obligations to post collateral under derivative instrument contracts. Certain derivative instrument contracts entered into by the Company are governed by master agreements, which contain credit-risk-related contingent features that would allow the counterparties to terminate the contracts early and request immediate payment should the Company trigger an event of default on other specified borrowings. The Company records all derivative instruments on a gross basis in the Consolidated Balance Sheets. Accordingly, there are no offsetting amounts that net assets against liabilities.

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The Effect of Derivative Instruments on the Consolidated Balance Sheets

Fair Values of Derivative Instruments

Derivatives Designated as Hedging Instruments

| (In millions) | Asset Derivatives December 31, 2018 | | December 31, 2017 | |
|------------------------------------|--|------------|---|------------|
| | Balance Sheet Location | Fair Value | Balance Sheet Location | Fair Value |
| Interest rate swaps | Prepaid expenses and other current assets | \$ 3.6 | Prepaid expenses and other current assets | \$ 16.2 |
| Foreign currency forward contracts | Prepaid expenses and other current assets | — | Prepaid expenses and other current assets | 63.4 |
| Total | | \$ 3.6 | | \$ 79.6 |
| | Liability Derivatives December 31, 2018 | | December 31, 2017 | |
| | Balance Sheet Location | Fair Value | Balance Sheet Location | Fair Value |
| Foreign currency forward contracts | Other current liabilities | \$ 12.1 | Other current liabilities | \$ — |
| | | \$ 12.1 | | \$ — |

The Effect of Derivative Instruments on the Consolidated Balance Sheets

Fair Values of Derivative Instruments

Derivatives Not Designated as Hedging Instruments

| (In millions) | Asset Derivatives December 31, 2018 | | December 31, 2017 | |
|------------------------------------|--|------------|---|------------|
| | Balance Sheet Location | Fair Value | Balance Sheet Location | Fair Value |
| Foreign currency forward contracts | Prepaid expenses and other current assets | \$ 30.2 | Prepaid expenses and other current assets | \$ 9.3 |
| Total | | \$ 30.2 | | \$ 9.3 |
| | Liability Derivatives December 31, 2018 | | December 31, 2017 | |
| (In millions) | Balance Sheet Location | Fair Value | Balance Sheet Location | Fair Value |
| Foreign currency forward contracts | Other current liabilities | \$ 17.3 | Other current liabilities | \$ 31.1 |
| Total | | \$ 17.3 | | \$ 31.1 |

Table of ContentsThe Effect of Derivative Instruments on the Consolidated Statements of Operations
Derivatives in Fair Value Hedging Relationships

| Location of Loss Recognized in Earnings on Derivatives | Amount of Loss Recognized in Earnings on Derivatives | | |
|--|--|----------|----------|
| | Year Ended December 31, | | |
| (In millions) | 2018 | 2017 | 2016 |
| Interest rate swaps Interest expense | \$(12.6) | \$(10.0) | \$(10.0) |
| Total | \$(12.6) | \$(10.0) | \$(10.0) |

| Location of Gain Recognized in Earnings on Hedged Items | Amount of Gain Recognized in Earnings on Hedging Items | | |
|---|---|--------|--------|
| | Year Ended December 31, | | |
| (In millions) | 2018 | 2017 | 2016 |
| 2023 Senior Notes (3.125% coupon) Interest expense | \$12.6 | \$10.0 | \$10.0 |
| Total | \$12.6 | \$10.0 | \$10.0 |

The Effect of Derivative Instruments on the Consolidated Statements of Comprehensive Earnings
Derivatives in Net Investment Hedging Relationships

| Location of Gain or (Loss) Recognized in AOCE (Net of Tax) on Derivatives (Effective Portion) | Amount of Gain or (Loss) Recognized in AOCE (Net of Tax) on Derivatives (Effective Portion) | | |
|---|---|-----------|---------|
| | Year Ended December 31, | | |
| (In millions) | 2018 | 2017 | 2016 |
| Foreign currency borrowings and forward contracts | \$108.9 | \$(238.4) | \$(1.4) |
| Total | \$108.9 | \$(238.4) | \$(1.4) |

The Effect of Derivative Instruments on the Consolidated Statements of Comprehensive Earnings
Derivatives in Cash Flow Hedging Relationships

| Location of (Loss) or Gain Recognized in AOCE (Net of Tax) on Derivatives (Effective Portion) | Amount of (Loss) or Gain Recognized in AOCE (Net of Tax) on Derivatives (Effective Portion) | | |
|---|---|--------|----------|
| | Year Ended December 31, | | |
| (In millions) | 2018 | 2017 | 2016 |
| Foreign currency forward contracts | \$(46.6) | \$28.1 | \$(27.5) |
| Interest rate swaps | — | — | (38.7) |
| Total | \$(46.6) | \$28.1 | \$(66.2) |

The Effect of Derivative Instruments on the Consolidated Statements of Operations
Derivatives in Cash Flow Hedging Relationships

| Location of Gain or (Loss) Reclassified from AOCE into Earnings (Loss) Reclassified (Effective Portion) | Amount of Gain or (Loss) Reclassified |
|--|--|
|--|--|

| (In millions) | | from AOCE into Earnings (Effective Portion) |
|---------------------------------------|------------------|---|
| | | Year Ended December 31, |
| | | 2018 2017 2016 |
| Foreign currency forward contracts | Net sales | \$6.2 \$1.1 \$(44.3) |
| Interest rate swaps | Interest expense | (7.7) (7.3) (8.7) |
| Total | | \$(1.5) \$(6.2) \$(53.0) |

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| (In millions) | Location of Loss Excluded from the Assessment of Hedge Effectiveness | Amount of Loss Excluded from the Assessment of Hedge Effectiveness Year Ended December 31, | |
|------------------------------------|--|--|---------|
| | | 2018 | 2017 |
| Foreign currency forward contracts | Other expense, net | \$ — | \$(3.3) |
| Total | | \$ — | \$(3.3) |

At December 31, 2018, the Company expects that approximately \$58.0 million of pre-tax net losses on cash flow hedges will be reclassified from AOCE into earnings during the next twelve months.

The Effect of Derivative Instruments on the Consolidated Statements of Operations

Derivatives Not Designated as Hedging Instruments

| (In millions) | Location of Gain or (Loss) Recognized in Earnings on Derivatives | Amount of Gain or (Loss) Recognized in Earnings on Derivatives Year Ended December 31, | | |
|---|--|--|--------|-----------|
| | | 2018 | 2017 | 2016 |
| Foreign currency option and forward contracts | Other expense, net | \$34.8 | \$47.7 | \$(104.5) |
| Total | | \$34.8 | \$47.7 | \$(104.5) |

Fair Value Measurement

Fair value is based on the price that would be received from the sale of an identical asset or paid to transfer an identical liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, a fair value hierarchy has been established that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2: Observable market-based inputs other than quoted prices in active markets for identical assets or liabilities.
- Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, as well as considers counterparty credit risk in its assessment of fair value.

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Financial assets and liabilities carried at fair value are classified in the tables below in one of the three categories described above:

| (In millions) | December 31, 2018 | | | Total |
|---|-------------------|---------|---------|---------|
| | Level 1 | Level 2 | Level 3 | |
| Recurring fair value measurements | | | | |
| Financial Assets | | | | |
| Cash equivalents: | | | | |
| Money market funds | \$71.0 | \$— | \$— | \$71.0 |
| Total cash equivalents | 71.0 | — | — | 71.0 |
| Equity securities: | | | | |
| Exchange traded funds | 31.7 | — | — | 31.7 |
| Marketable securities | 0.8 | — | — | 0.8 |
| Total equity securities | 32.5 | — | — | 32.5 |
| Available-for-sale fixed income investments: | | | | |
| Corporate bonds | — | 9.9 | — | 9.9 |
| U.S. Treasuries | — | 9.4 | — | 9.4 |
| Agency mortgage-backed securities | — | 1.6 | — | 1.6 |
| Asset backed securities | — | 3.2 | — | 3.2 |
| Other | — | 0.9 | — | 0.9 |
| Total available-for-sale fixed income investments | — | 25.0 | — | 25.0 |
| Foreign exchange derivative assets | — | 30.2 | — | 30.2 |
| Interest rate swap derivative assets | — | 3.6 | — | 3.6 |
| Total assets at recurring fair value measurement | \$103.5 | \$58.8 | \$— | \$162.3 |
| Financial Liabilities | | | | |
| Foreign exchange derivative liabilities | \$— | \$29.4 | \$— | \$29.4 |
| Contingent consideration | — | — | 355.3 | 355.3 |
| Total liabilities at recurring fair value measurement | \$— | \$29.4 | \$355.3 | \$384.7 |

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| (In millions) | December 31, 2017 | | | Total |
|---|-------------------|---------|---------|---------|
| | Level 1 | Level 2 | Level 3 | |
| Recurring fair value measurements | | | | |
| Financial Assets | | | | |
| Cash equivalents: | | | | |
| Money market funds | \$8.4 | \$— | \$— | \$8.4 |
| Total cash equivalents | 8.4 | — | — | 8.4 |
| Equity securities: | | | | |
| Exchange traded funds | 33.9 | — | — | 33.9 |
| Marketable securities | 45.2 | — | — | 45.2 |
| Total equity securities | 79.1 | — | — | 79.1 |
| Available-for-sale fixed income investments: | | | | |
| Corporate bonds | — | 16.5 | — | 16.5 |
| U.S. Treasuries | — | 7.4 | — | 7.4 |
| Agency mortgage-backed securities | — | 4.1 | — | 4.1 |
| Asset backed securities | — | 2.1 | — | 2.1 |
| Other | — | 1.4 | — | 1.4 |
| Total available-for-sale fixed income investments | — | 31.5 | — | 31.5 |
| Foreign exchange derivative assets | — | 72.7 | — | 72.7 |
| Interest rate swap derivative assets | — | 16.2 | — | 16.2 |
| Total assets at recurring fair value measurement | \$87.5 | \$120.4 | \$— | \$207.9 |
| Financial Liabilities | | | | |
| Foreign exchange derivative liabilities | \$— | \$31.1 | \$— | \$31.1 |
| Contingent consideration | — | — | 453.7 | 453.7 |
| Total liabilities at recurring fair value measurement | \$— | \$31.1 | \$453.7 | \$484.8 |

For financial assets and liabilities that utilize Level 2 inputs, the Company utilizes both direct and indirect observable price quotes, including the LIBOR yield curve, foreign exchange forward prices, and bank price quotes. For the years ended December 31, 2018 and 2017, there were no transfers between Level 1 and 2 of the fair value hierarchy. Below is a summary of valuation techniques for Level 1 and Level 2 financial assets and liabilities:

• Cash equivalents — valued at observable net asset value prices.

• Equity securities, exchange traded funds — valued at the active quoted market prices from broker or dealer quotations or transparent pricing sources at the reporting date. Unrealized gains and losses attributable to changes in fair value are included in other expense, net, in the Consolidated Statements of Operations.

• Equity securities, marketable securities — valued using quoted stock prices from public exchanges at the reporting date. Unrealized gains and losses attributable to changes in fair value are included in other expense, net, in the Consolidated Statements of Operations.

• Available-for-sale fixed income investments — valued at the quoted market prices from broker or dealer quotations or transparent pricing sources at the reporting date. Unrealized gains and losses attributable to changes in fair value, net of income taxes, are included in accumulated other comprehensive loss as a component of shareholders' equity.

• Interest rate swap derivative assets and liabilities — valued using the LIBOR/EURIBOR yield curves at the reporting date. Counterparties to these contracts are highly rated financial institutions.

• Foreign exchange derivative assets and liabilities — valued using quoted forward foreign exchange prices and spot rates at the reporting date. Counterparties to these contracts are highly rated financial institutions.

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Contingent Consideration

The fair value measurement of contingent consideration is determined using Level 3 inputs. The Company's contingent consideration represents a component of the total purchase consideration for the respiratory delivery platform, the acquisitions of Agila, certain female healthcare businesses from Famy Care Limited (such businesses "Jai Pharma Limited") and the Topicals Business and certain other acquisitions. The measurement is calculated using unobservable inputs based on the Company's own assumptions. For the respiratory delivery platform, Jai Pharma Limited and certain other acquisitions, significant unobservable inputs in the valuation include the probability and timing of future development and commercial milestones and future profit sharing payments. When valuing the contingent consideration related to the respiratory delivery platform and Jai Pharma Limited, the value of the obligations is derived from a probability assessment based on expectations of when certain milestones or profit share payments occur which are discounted using a market rate of return. At December 31, 2018 and 2017, discount rates ranging from 2.1% to 11.0% were utilized in the valuations. Significant changes in unobservable inputs could result in material changes to the contingent consideration liability.

A rollforward of the activity in the Company's fair value of contingent consideration from December 31, 2016 to December 31, 2018 is as follows:

| (In millions) | Current Portion (1) | Long-Term Portion (2) | Total Contingent Consideration |
|------------------------------|---------------------|-----------------------|--------------------------------|
| Balance at December 31, 2016 | \$256.9 | \$ 307.7 | \$ 564.6 |
| Payments | (77.3) | (0.2) | (77.5) |
| Reclassifications | 27.0 | (27.0) | — |
| Accretion | — | 25.9 | 25.9 |
| Fair value gain (3) | (38.8) | (20.5) | (59.3) |
| Balance at December 31, 2017 | \$167.8 | \$ 285.9 | \$ 453.7 |
| Payments | (82.9) | — | (82.9) |
| Reclassifications | 62.1 | (62.1) | — |
| Accretion | — | 19.8 | 19.8 |
| Fair value loss (gain) (3) | 11.3 | (46.6) | (35.3) |
| Balance at December 31, 2018 | \$158.3 | \$ 197.0 | \$ 355.3 |

(1) Included in other current liabilities on the Consolidated Balance Sheets.

(2) Included in other long-term obligations on the Consolidated Balance Sheets.

(3) Included in litigation settlements and other contingencies, net in the Consolidated Statements of Operations.

2017 Changes to Contingent Consideration: During the year ended December 31, 2017, the Company recorded a fair value gain of \$93.5 million related to the respiratory delivery platform contingent consideration partially offset by fair value losses of \$9.9 million related to Jai Pharma Limited contingent consideration and \$23.5 million related to the Topicals Business contingent consideration. In addition, the Company made payments of approximately \$13.7 million related to the Agila contingent consideration, a net payment of \$40 million to resolve the Topicals Business contingent consideration and a payment of approximately \$20.0 million related to the Jai Pharma Limited contingent consideration.

2018 Changes to Contingent Consideration: During the year ended December 31, 2018, the Company recorded a fair value gain of \$44.0 million related to the respiratory delivery platform contingent consideration partially offset by fair value losses of \$8.6 million related to the Jai Pharma Limited contingent consideration. In addition, the Company made payments of approximately \$51.0 million to resolve the Agila contingent consideration and a net payment of \$30.0 million to resolve the Jai Pharma Limited contingent consideration.

The Company expects to incur approximately \$15 million to \$20 million of non-cash accretion expense related to the increase in the net present value of the contingent consideration liabilities in 2019.

Although the Company has not elected the fair value option for financial assets and liabilities, any future transacted financial asset or liability will be evaluated for the fair value election.

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Available-for-Sale Securities

The amortized cost and estimated fair value of available-for-sale fixed income securities, included in prepaid expenses and other current assets, were as follows:

| (In millions) | Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|----------------------------------|--------|------------------------------|-------------------------------|---------------|
| December 31, 2018 ⁽¹⁾ | | | | |
| Debt securities | \$24.8 | \$ 0.2 | \$ — | \$25.0 |
| | \$24.8 | \$ 0.2 | \$ — | \$25.0 |
| December 31, 2017 | | | | |
| Debt securities | \$31.5 | \$ — | \$ — | \$31.5 |
| Equity securities | 29.5 | 16.9 | (1.2) | 45.2 |
| | \$61.0 | \$ 16.9 | \$ (1.2) | \$76.7 |

⁽¹⁾ Equity securities are no longer classified as available-for-sale as of January 1, 2018 as a result of the adoption of ASU 2016-01. Refer to Note 2 Summary of Significant Accounting Policies for additional information.

Maturities of available-for-sale debt securities at fair value as of December 31, 2018, were as follows:

| (In millions) | |
|--------------------------------|--------|
| Mature within one year | \$3.1 |
| Mature in one to five years | 13.4 |
| Mature in five years and later | 8.5 |
| | \$25.0 |

9. Debt

Short-Term Borrowings

| (In millions) | December 31, 2018 | December 31, 2017 |
|-----------------------|----------------------|----------------------|
| Receivables Facility | \$ — | \$ 45.0 |
| Other | 1.9 | 1.5 |
| Short-term borrowings | \$ 1.9 | \$ 46.5 |

Receivables Facility

The Company has a \$400 million Receivables Facility, which expires on March 25, 2019.

Under the terms of the Receivables Facility, our subsidiary, MPI, sells certain accounts receivable to Mylan Securitization LLC (“Mylan Securitization”), a wholly-owned special purpose entity which in turn sells a percentage ownership interest in the receivables to financial institutions and commercial paper conduits sponsored by financial institutions. MPI is the servicer of the receivables under the Receivables Facility. Purchases under the Receivables Facility will be repaid as accounts receivable are collected, with new purchases being advanced as new accounts receivable are originated by MPI. Mylan Securitization’s assets have been pledged to The Bank of Tokyo-Mitsubishi UFJ, Ltd., as agent, in support of its obligations under the Receivables Facility. Any amounts outstanding under the facility are recorded as borrowings and the underlying receivables will continue to be included in accounts receivable, net, in the Consolidated Balance Sheets of the Company.

The Receivables Facility contains requirements relating to the performance of the accounts receivable and covenants related to the Company with which the Company was compliant as of December 31, 2018. As of December 31, 2018 and 2017, the Company had \$322.0 million and \$1.04 billion, respectively, of accounts receivable balances sold to Mylan Securitization.

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Commercial Paper Program

On July 27, 2018, the Company established an unsecured commercial paper program (the “Commercial Paper Program”) pursuant to which Mylan Inc. may issue short-term, unsecured commercial paper notes (the “CP Notes”) that are guaranteed by the Company pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), which replaced Mylan N.V.’s existing commercial paper program established June 8, 2017 (the “Existing Commercial Paper Program”) on substantially identical terms to the Existing Commercial Paper Program. Amounts available under the Commercial Paper Program may be borrowed, repaid and re-borrowed from time to time, with the aggregate principal amount of the commercial paper notes outstanding under the Commercial Paper Program at any time not to exceed \$1.65 billion. The Company’s 2018 Revolving Facility (as defined below) will be available to pay the CP Notes, if necessary. The maturities of the CP Notes will vary but will not exceed 364 days from the date of issue.

The Company uses net proceeds from its Commercial Paper Program and the Receivables Facility as a source of liquidity for general corporate purposes, including for business development transactions, working capital and share repurchases. Commercial paper borrowings and the Receivables Facility may vary during a particular period, as a result of fluctuations in working capital requirements and timing of cash receipts.

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Long-Term Debt

A summary of long-term debt is as follows:

| (In millions) | Coupon | December 31, 2018 | December 31, 2017 |
|---|--------|----------------------|----------------------|
| Current portion of long-term debt: | | | |
| 2016 Term Facility ^{(a) **} | 3.897% | \$ 100.0 | \$ — |
| 2018 Senior Notes * | 2.600% | — | 649.9 |
| 2018 Floating Rate Euro Notes ^{(b) **} | | — | 600.2 |
| 2018 Senior Notes ** | 3.000% | — | 499.8 |
| 2019 Senior Notes ** | 2.500% | 549.9 | — |
| Other | | 6.2 | 2.4 |
| Deferred financing fees | | (0.9 |) (3.1 |
| Current portion of long-term debt | | \$ 655.2 | \$ 1,749.2 |

Non-current portion of long-term debt:

| | | | |
|---|--------|-------------|-------------|
| 2016 Term Facility ^{(a) **} | 3.897% | \$ — | \$ 100.0 |
| 2019 Senior Notes ** | 2.500% | — | 999.5 |
| 2019 Senior Notes * | 2.550% | — | 499.7 |
| 2020 Floating Rate Euro Notes ^{(c) **} | | 573.3 | 600.2 |
| 2020 Euro Senior Notes ** | 1.250% | 858.1 | 897.6 |
| 2020 Senior Notes ** | 3.750% | 499.9 | 499.9 |
| 2021 Senior Notes ** | 3.150% | 2,248.7 | 2,248.2 |
| 2023 Senior Notes * | 3.125% | 752.9 | 765.4 |
| 2023 Senior Notes * | 4.200% | 498.9 | 498.8 |
| 2024 Euro Senior Notes ** | 2.250% | 1,144.2 | 1,197.7 |
| 2025 Euro Senior Notes * | 2.125% | 572.0 | — |
| 2026 Senior Notes ** | 3.950% | 2,236.5 | 2,235.0 |
| 2028 Euro Senior Notes ** | 3.125% | 852.5 | 892.0 |
| 2028 Senior Notes * | 4.550% | 748.2 | — |
| 2043 Senior Notes * | 5.400% | 497.2 | 497.1 |
| 2046 Senior Notes ** | 5.250% | 999.8 | 999.8 |
| 2048 Senior Notes * | 5.200% | 747.6 | — |
| Other | | 5.1 | 6.3 |
| Deferred financing fees | | (73.7 |) (71.9 |
| Long-term debt | | \$ 13,161.2 | \$ 12,865.3 |

^(a) The 2016 Term Facility bears interest at LIBOR plus a base rate, which margins can fluctuate based on the Company's credit ratings.

^(b) Interest rate of the instrument was three-month EURIBOR plus 0.870% per annum, reset quarterly.

^(c) Instrument bears interest at a rate of three-month EURIBOR plus 0.50% per annum, reset quarterly.

* Instrument was issued by Mylan Inc.

** Instrument was issued by Mylan N.V.

2016 Revolving Facility, 2018 Revolving Facility and 2016 Term Facility

On November 22, 2016, the Company entered into a revolving credit facility among the Company, as borrower, Mylan Inc., as a guarantor, certain lenders and issuing banks and Bank of America, N.A., as the administrative agent, pursuant to which the Company may obtain extensions of credit in an aggregate principal amount not to exceed \$2.0 billion (the "2016

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Revolving Facility”). On the same day, the Company entered into a term credit facility among the Company, as borrower, Mylan Inc., as a guarantor, certain lenders and Goldman Sachs Bank USA, as administrative agent, pursuant to which the Company has \$100.0 million outstanding in term loans (the “2016 Term Facility”) at December 31, 2018. On July 27, 2018, the Company entered into a revolving credit facility among Mylan Inc., as borrower, the Company, as a guarantor, certain lenders and issuing banks and Bank of America, N.A., as the administrative agent, which replaced the 2016 Revolving Facility on substantially identical terms to the 2016 Revolving Facility and pursuant to which Mylan Inc. may obtain extensions of credit in an aggregate principal amount not to exceed \$2.0 billion (the “2018 Revolving Facility”).

The 2016 Term Facility and the 2018 Revolving Facility each contain customary affirmative covenants for facilities of this type, including among others, covenants pertaining to the delivery of financial statements, notices of default and certain material events, maintenance of corporate existence and rights, property, and insurance and compliance with laws, as well as customary negative covenants for facilities of this type, including limitations on the incurrence of subsidiary indebtedness, liens, mergers and certain other fundamental changes, investments and loans, acquisitions, transactions with affiliates, payments of dividends and other restricted payments and changes in our lines of business. The 2016 Term Facility and 2018 Revolving Facility contain a maximum consolidated leverage ratio financial covenant requiring maintenance of a maximum ratio of 3.75 to 1.00 for consolidated total indebtedness as of the end of any quarter to consolidated EBITDA for the trailing four quarters as defined in the related credit agreements (“leverage ratio”).

The 2016 Term Facility was amended in November 2017 to allow a leverage ratio of 4.25 to 1.00 through the December 31, 2018 reporting period and a leverage ratio of 3.75 to 1.00 thereafter. The 2018 Revolving Facility similarly provides for a leverage ratio of 4.25 to 1.00 through the December 31, 2018 reporting period and a leverage ratio of 3.75 to 1.00 thereafter. On February 22, 2019, the Company, as a guarantor, and Mylan Inc., as borrower, entered into an amendment (the "Revolving Loan Amendment") to the 2018 Revolving Facility. In addition, on February 22, 2019, the Company entered into an amendment (the "Term Loan Amendment") to the 2016 Term Facility. The Revolving Loan Amendment and the Term Loan Amendment extended the leverage ratio covenant of 4.25 to 1.00 through the December 31, 2019 reporting period, with a leverage ratio of 3.75 to 1.00 thereafter. The Company is in compliance at December 31, 2018 and expects to remain in compliance for the next twelve months.

Senior Notes**Issuance of 2018 Senior Notes**

The following table provides the amounts of senior unsecured debt issued by Mylan Inc. and guaranteed by Mylan N.V., on April 9, 2018 (the “April 2018 Senior Notes”). The April 2018 Senior Notes were issued pursuant to an indenture dated April 9, 2018. The April 2018 Senior Notes were issued in a private offering exempt from the registration requirements of the Securities Act to qualified institutional buyers in accordance with Rule 144A under the Securities Act and to persons outside of the U.S. pursuant to Regulation S under the Securities Act. The Company has entered into a registration rights agreement, dated as of April 9, 2018 pursuant to which Mylan Inc. and Mylan N.V. are required to use commercially reasonable efforts to file a registration statement with respect to an offer to exchange each series of the April 2018 Senior Notes for new notes with the same aggregate principal amount and terms substantially identical in all material respects.

| (In millions) | Interest Rate | Principal Amount |
|----------------------------------|---------------|------------------|
| 2028 Senior Notes ⁽¹⁾ | 4.550% | \$750.0 |
| 2048 Senior Notes ⁽¹⁾ | 5.200% | 750.0 |
| Total April 2018 Senior Notes | | \$1,500.0 |

⁽¹⁾ Redeemable, in whole or in part, at our option at any time prior to three months (in the case of the 2028 Senior Notes) or six months (in the case of the 2048 Senior Notes) of the maturity date at the greater of 100% of the principal amount or the sum of the present values of the remaining scheduled payments of principal and interest discounted at the U.S. Treasury rate plus an incremental spread of 0.30% (in the case of the 2028

Senior Notes) or 0.35% (in the case of the 2048 Senior Notes), plus, in each case, accrued and unpaid interest.

On April 28, 2018, the Company redeemed all of the outstanding \$650 million principal amount of Mylan Inc.'s 2.600% senior notes due 2018, all of the outstanding \$500 million principal amount of Mylan N.V.'s 3.000% senior notes due

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2018 and \$350 million of the outstanding \$500 million principal amount of Mylan Inc.'s 2.550% senior notes due 2019. The redemption of these notes was funded with the net proceeds from the April 2018 Senior Notes offering. In November 2018, Mylan N.V. and Mylan Inc. filed a registration statement with the Securities and Exchange Commission ("SEC") with respect to an offer to exchange these notes for registered notes with the same aggregate principal amount and terms substantially identical in all material respects, which was declared effective on December 11, 2018. The exchange offer expired on January 9, 2019 and settled on January 10, 2019. 100% of each of the 4.550% Senior Notes due 2028 and the 5.200% Senior Notes due 2048 were exchanged.

Issuance of 2018 Euro Senior Notes

On May 23, 2018, Mylan Inc. completed the offering of €500 million aggregate principal amount of its 2.125% Euro Senior Notes due 2025 (the "May 2018 Euro Senior Notes"). The May 2018 Euro Senior Notes were issued pursuant to an indenture dated May 23, 2018. The May 2018 Euro Senior Notes are guaranteed by Mylan N.V. and were issued in a private offering exempt from the registration requirements of the Securities Act, to persons outside of the U.S. pursuant to Regulation S under the Securities Act. The May 2018 Euro Senior Notes are redeemable, in whole or in part, at our option at any time prior to three months of the maturity date at the greater of 100% of the principal amount or the sum of the present values of the remaining scheduled payments of principal and interest discounted at the applicable Bund Rate plus an incremental spread of 0.30%, plus, in each case, accrued and unpaid interest.

On June 15, 2018, the Company redeemed the remaining \$150 million outstanding principal amount of Mylan Inc.'s 2.550% Senior Notes due 2019 and \$450 million of the outstanding \$1.0 billion principal amount of Mylan N.V.'s 2.500% Senior Notes due 2019. The redemption of these notes was funded with the net proceeds from the May 2018 Euro Senior Notes offering.

Issuance of 2017 Euro Senior Notes

On May 24, 2017, the Company completed its offering of €500 million aggregate principal amount of Floating Rate Senior Notes due 2020 (the "May 2017 Floating Rate Euro Senior Notes"), issued pursuant to the indenture dated May 24, 2017 (the "2017 Euro Notes Indenture"). The May 2017 Floating Rate Euro Senior Notes will mature on May 24, 2020 and cannot be redeemed prior to maturity at the option of the Company.

The May 2017 Floating Rate Euro Senior Notes were issued in a private offering exempt from the registration requirements of the Securities Act to persons outside of the U.S. pursuant to Regulation S under the Securities Act. The May 2017 Floating Rate Euro Senior Notes are the Company's senior unsecured indebtedness and are guaranteed on a senior unsecured basis by Mylan Inc.

The May 2017 Floating Rate Euro Senior Notes bear interest at a rate per annum, reset quarterly, equal to the sum of (i) three-month EURIBOR (as defined in the 2017 Euro Notes Indenture) plus (ii) 0.50%, provided, however, that the minimum interest rate is zero. Interest on the May 2017 Floating Rate Euro Senior Notes is payable quarterly in arrears on each February 24, May 24, August 24 and November 24. The interest rate at December 31, 2018 was approximately 0.17% per annum.

The Company utilized the net proceeds from the May 2017 Floating Rate Euro Senior Notes offering to repay a portion of the term loans under the 2016 Term Facility and to pay associated fees and expenses.

Fair Value

At December 31, 2018 and 2017, the aggregate fair value of the Company's outstanding notes was approximately \$13.10 billion and \$14.93 billion, respectively. The fair values of the outstanding notes were valued at quoted market prices from broker or dealer quotations and were classified as Level 2 in the fair value hierarchy. Based on quoted market rates of interest and maturity schedules of similar debt issues, the fair value of the Company's 2016 Term Facility determined based on Level 2 inputs, approximates its carrying value at December 31, 2018 and 2017.

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Mandatory minimum repayments remaining on the outstanding long-term debt at December 31, 2018, excluding the discounts and premiums, are as follows for each of the periods ending December 31:

| | |
|---------------------|-----------|
| (In millions) Total | |
| 2019 | \$ 650 |
| 2020 | 1,933 |
| 2021 | 2,250 |
| 2022 | — |
| 2023 | 1,250 |
| Thereafter | 7,830 |
| Total | \$ 13,913 |

10. Comprehensive Earnings

Accumulated other comprehensive loss, as reflected on the Consolidated Balance Sheets, is comprised of the following:

| | | |
|--|----------------------|----------------------|
| (In millions) | December 31, 2018 | December 31, 2017 |
| Accumulated other comprehensive loss: | | |
| Net unrealized gain on marketable securities, net of tax | \$ — | \$ 10.1 |
| Net unrecognized gains and prior service cost related to defined benefit plans, net of tax | 1.7 | 6.0 |
| Net unrecognized losses on derivatives in cash flow hedging relationships, net of tax | (53.1) | (3.7) |
| Net unrecognized losses on derivatives in net investment hedging relationships, net of tax | (130.9) | (239.8) |
| Foreign currency translation adjustment | (1,259.0) | (133.8) |
| | \$ (1,441.3) | \$ (361.2) |

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Components of accumulated other comprehensive (loss) earnings, before tax, consist of the following:

| | Year Ended December 31, 2018 | | | | | | Totals |
|--|--|---|---|----------------------------|---|--|--------|
| | Gains and Losses on Derivatives in Cash Flow Hedging Relationships | Gains and Losses on Net Investment Hedges | Gains and Losses on Marketable Securities | Defined Pension Plan Items | Foreign Currency Translation Adjustment | | |
| (In millions) | Foreign Currency Forward Contracts | Interest Rate Swaps | | | | | |
| | | Total | | | | | |
| Balance at December 31, 2017, net of tax | | | | | | | |
| Other comprehensive (loss) earnings before reclassifications, before tax | | | | | | | |
| Amounts reclassified from accumulated other comprehensive (loss) earnings, before tax: | | | | | | | |
| Gain on foreign exchange forward contracts classified as cash flow hedges, included in net sales | | | | | | | |
| Loss on interest rate swaps classified as cash flow hedges, included in interest expense | | | | | | | |
| Amortization of prior service costs included in SG&A | | | | | | | |
| Amortization of actuarial loss included in SG&A | | | | | | | |
| Net other comprehensive (loss) earnings, before tax | | | | | | | |
| Income tax (benefit) provision | | | | | | | |
| Cumulative effect of the adoption of new accounting standards | | | | | | | |
| Balance at December 31, 2018, net of tax | | | | | | | |

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| (In millions) | Year Ended December 31, 2017 | | | | | | Totals | |
|--|--|---|---|----------------------------|---|----------|--------------|-------------|
| | Gains and Losses on Derivatives in Cash Flow Hedging Relationships | Gains and Losses on Net Investment Hedges | Gains and Losses on Marketable Securities | Defined Pension Plan Items | Foreign Currency Translation Adjustment | | | |
| | Foreign Currency Forward Contracts | Interest Rate Swaps | Total | | | | | |
| Balance at December 31, 2016, net of tax | | | \$(38.6) | \$(1.4) | \$ 14.5 | \$(0.5) | \$(2,237.7) | \$(2,263.7) |
| Other comprehensive (loss) earnings before reclassifications, before tax | | | 46.5 | (238.4) | (6.7) | 2.9 | 2,103.9 | 1,908.2 |
| Amounts reclassified from accumulated other comprehensive (loss) earnings, before tax: | | | | | | | | |
| Loss on foreign exchange forward contracts classified as cash flow hedges, included in net sales | | | (1.1) | | | | | (1.1) |
| Loss on interest rate swaps classified as cash flow hedges, included in interest expense | 7.3 | | 7.3 | | | | | 7.3 |
| Amortization of prior service costs included in SG&A | | | | | | 0.2 | | 0.2 |
| Amortization of actuarial gain included in SG&A | | | | | | 0.7 | | 0.7 |
| Net other comprehensive (loss) earnings, before tax | | | 52.7 | (238.4) | (6.7) | 3.8 | 2,103.9 | 1,915.3 |
| Income tax (benefit) provision | | | 17.8 | — | (2.3) | (2.7) | — | 12.8 |
| Balance at December 31, 2017, net of tax | | | \$(3.7) | \$(239.8) | \$ 10.1 | \$ 6.0 | \$(133.8) | \$(361.2) |

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| (In millions) | Year Ended December 31, 2016 | | | | | | Totals | |
|--|--|---|---|----------------------------|---|-----------|--------------|-------------|
| | Gains and Losses on Derivatives in Cash Flow Hedging Relationships | Gains and Losses on Net Investment Hedges | Gains and Losses on Marketable Securities | Defined Pension Plan Items | Foreign Currency Translation Adjustment | | | |
| | Foreign Currency Forward Contracts | Interest Rate Swaps | Total | | | | | |
| Balance at December 31, 2015, net of tax | | | \$(18.1) | \$ — | \$ (1.0) | \$(14.9) | \$(1,730.3) | \$(1,764.3) |
| Other comprehensive earnings (loss) before reclassifications, before tax | | | (84.2) | (1.8) | 24.6 | 20.0 | (507.4) | (548.8) |
| Amounts reclassified from accumulated other comprehensive loss, before tax: | | | | | | | | |
| Loss on foreign exchange forward contracts classified as cash flow hedges, included in net sales | (44.3) | | 44.3 | | | | | 44.3 |
| Loss on interest rate swaps classified as cash flow hedges, included in interest expense | | (8.7) | 8.7 | | | | | 8.7 |
| Amortization of prior service costs included in SG&A | | | | | | 0.3 | | 0.3 |
| Amortization of actuarial gain included in SG&A | | | | | | 1.1 | | 1.1 |
| Net other comprehensive loss, before tax | | | (31.2) | (1.8) | 24.6 | 21.4 | (507.4) | (494.4) |
| Income tax provision (benefit) | | | (10.7) | (0.4) | 9.1 | 7.0 | — | 5.0 |
| Balance at December 31, 2016, net of tax | | | \$(38.6) | \$ (1.4) | \$ 14.5 | \$(0.5) | \$(2,237.7) | \$(2,263.7) |

11. Income Taxes

On December 22, 2017, the U.S. government enacted the Tax Act. The Tax Act makes broad and complex changes to the Code including, but not limited to, reducing the U.S. federal corporate income tax rate and requiring a one-time transition tax on certain unrepatriated earnings of non-U.S. corporate subsidiaries of large U.S. shareholders that may electively be paid over eight years. While the Tax Act reduces the U.S. federal corporate income tax rate from 35% to 21% for tax years beginning after December 31, 2017, ASC Topic 740 required the Company to remeasure its deferred tax balances at December 31, 2017 in accordance with the 2018 rate reduction.

The Tax Act also puts in place new tax laws that impact our taxable income beginning in 2018, which include, but are not limited to (1) creating a Base Erosion Anti-Abuse Tax (“BEAT”), which is a new minimum tax, (2) generally eliminating U.S. federal income taxes on dividends from foreign subsidiaries, (3) a new provision designed to tax currently global intangible low-taxed income (“GILTI”) earned by non-U.S. corporate subsidiaries of large U.S. shareholders and a deduction generally equal to 50 percent of GILTI (37.5 percent for tax years beginning after December 31, 2025) to offset the income tax liability, (4) a provision limiting the amount of deductible interest expense in the U.S., (5) the repeal of the domestic manufacturing deduction, (6) limitations on the deductibility of certain executive compensation, and (7) limitations on the utilization of foreign tax credits to reduce the U.S. income tax liability.

Shortly after the Tax Act was enacted, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (“SAB 118”) which provided guidance on accounting for the Tax Act’s impact. SAB 118 provides a measurement period, which in no case should extend beyond one year from the Tax Act enactment date, during which a company acting in good faith may complete the accounting for the impacts of the Tax Act under ASC Topic 740.

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To the extent that the accounting for certain income tax effects of the Tax Act is incomplete, a company can determine a reasonable estimate for those effects and record a provisional estimate in the financial statements in the first reporting period in which a reasonable estimate can be determined. The Company recorded a provisional net tax charge of \$128.6 million related to the Tax Act in the year ended December 31, 2017. This net charge primarily consisted of a net expense of \$15.0 million due to the remeasurement of our net deferred tax accounts to reflect the U.S. federal corporate income tax rate reduction to 21% and a net expense for the transition tax of \$113.6 million. The transition tax is a 2017 tax on the previously untaxed accumulated and current earnings and profits of certain of our foreign subsidiaries, which the Company expects to pay, net of certain tax attributes and credit carryforwards, over eight years beginning in 2018.

Proposed regulations issued by the U.S. Department of the Treasury on August 1, 2018, provided further interpretive guidance on the transition tax. During the year ended December 31, 2018, the Company revised its estimated liability for the transition tax from \$113.6 million to \$99.1 million. The \$14.5 million benefit was recorded as a component of the Company's tax provision during the year ended December 31, 2018.

The Tax Act includes a provision designed to currently tax GILTI earned by non-U.S. corporate subsidiaries of large U.S. shareholders starting in 2018. The Company has elected, as permitted in FASB Staff Q&A - Topic 740 - No. 5, to treat any future GILTI tax liabilities as period costs and will expense those liabilities in the period incurred. The Company has not recorded deferred taxes associated with the GILTI provision of the Tax Act.

As of December 31, 2018, the Company's practice and intention was to reinvest the earnings in our non-U.S. subsidiaries outside of the U.S., and no U.S. deferred income taxes or foreign withholding taxes were recorded. The transition tax noted above resulted in the previously untaxed foreign earnings of U.S. subsidiaries being included in the federal and state taxable income. We analyze on an ongoing basis our global working capital requirements and the potential tax liabilities that would be incurred if the non-U.S. subsidiaries repatriate cash, which include potential local country withholding taxes and U.S. state taxation.

The Company's accounting for the impact of the 2017 Tax Act was completed during the year ended December 31, 2018. However, the Company continues to analyze the provisions of the Tax Act. Subsequent to the enactment of the Tax Act, additional guidance was issued by the U.S. Department of the Treasury, including Notices, Proposed Regulations, and Final Regulations. Further guidance may be issued in 2019 which could impact our interpretations of the Tax Act and materially impact the amounts recorded related to the Tax Act.

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The income tax provision (benefit) consisted of the following components:

| (In millions) | Year Ended December 31, | | |
|------------------------------------|-------------------------|----------|-----------|
| | 2018 | 2017 | 2016 |
| U.S. Federal: | | | |
| Current | \$(68.2) | \$39.5 | \$86.8 |
| Deferred | (112.9) | 28.2 | (303.8) |
| | (181.1) | 67.7 | (217.0) |
| U.S. State: | | | |
| Current | 6.8 | 3.9 | 13.8 |
| Deferred | (12.3) | (0.6) | (14.8) |
| | (5.5) | 3.3 | (1.0) |
| Non-U.S.: | | | |
| Current | 271.6 | 275.0 | 150.6 |
| Deferred | (139.1) | (139.0) | (290.9) |
| | 132.5 | 136.0 | (140.3) |
| Income tax (benefit) provision | \$(54.1) | \$207.0 | \$(358.3) |
| Earnings before income taxes: | | | |
| United Kingdom | \$1,259.8 | \$89.7 | \$(129.4) |
| United States | (1,000.5) | (414.5) | (187.4) |
| Foreign - Other | 39.1 | 1,227.8 | 438.5 |
| Total earnings before income taxes | \$298.4 | \$903.0 | \$121.7 |

For all periods presented, the allocation of earnings before income taxes between U.S. and non-U.S. operations includes intercompany interest allocations between certain domestic and foreign subsidiaries. These amounts are eliminated on a consolidated basis.

Temporary differences and carry-forwards that result in deferred tax assets and liabilities were as follows:

| (In millions) | December 31, December 31, | |
|------------------------------------|---------------------------|--------------|
| | 2018 | 2017 |
| Deferred tax assets: | | |
| Employee benefits | \$ 184.8 | \$ 215.0 |
| Litigation reserves | 15.7 | 45.3 |
| Accounts receivable allowances | 217.7 | 251.7 |
| Tax credit and loss carry-forwards | 891.4 | 849.9 |
| Interest expense | 373.5 | 151.7 |
| Intangible assets | 104.1 | 114.9 |
| Other | 182.4 | 212.4 |
| | 1,969.6 | 1,840.9 |
| Less: Valuation allowance | (806.0) | (662.8) |
| Total deferred tax assets | 1,163.6 | 1,178.1 |
| Deferred tax liabilities: | | |
| Plant and equipment | 105.6 | 120.7 |
| Intangible assets and goodwill | 2,189.2 | 2,538.2 |
| Other | 18.7 | 34.8 |
| Total deferred tax liabilities | 2,313.5 | 2,693.7 |
| Deferred tax liabilities, net | \$(1,149.9) | \$(1,515.6) |

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For those foreign subsidiaries whose investments are permanent in duration, income and foreign withholding taxes have not been provided on the amount by which the investment in those subsidiaries, as recorded for U.S. GAAP purposes, exceeds the tax basis. This amount may become taxable upon a repatriation of assets from the subsidiary or a sale or liquidation of the subsidiary. The amount of such temporary differences is approximately \$1.8 billion at December 31, 2018. Determination of the amount of any unrecognized deferred income tax liability on this temporary difference is not practicable as such determination involves material uncertainties about the potential extent and timing of any distributions, the availability and complexity of calculating foreign tax credits, and the potential indirect tax consequences of such distributions, including withholding taxes. No deferred taxes have been recorded on the instances whereby the Company's investment in foreign subsidiaries is currently greater for tax purposes than for U.S. GAAP purposes, as management has no current plans that would cause that temporary difference to reverse in the foreseeable future.

A reconciliation of the UK statutory tax rate of 19% to the effective tax rate is as follows:

| | Year Ended December 31, | | | |
|---|-------------------------|---------|----------|--|
| | 2018 | 2017 | 2016 | |
| Statutory tax rate | 19.0 % | 19.0 % | 20.0 % | |
| United States Operations | | | | |
| Clean energy and research credits | (33.1)% | (10.1)% | (85.9)% | |
| U.S. rate differential | (5.4)% | 7.4 % | (36.9)% | |
| Tax Act - transition tax & deferred tax rate change | (4.9)% | 8.4 % | — % | |
| Uncertain tax positions | (22.5)% | 1.0 % | 2.2 % | |
| State income taxes and credits | (3.2)% | (0.6)% | (8.1)% | |
| Valuation allowance | 54.2 % | 10.3 % | 4.4 % | |
| Global intangible low-taxed income | 8.6 % | — % | — % | |
| Other U.S. items | 7.5 % | 0.2 % | 1.3 % | |
| Other Foreign Operations | | | | |
| Luxembourg | (28.3)% | (10.1)% | (52.6)% | |
| Luxembourg — U.S. Branch | — % | — % | (28.8)% | |
| Gibraltar | (19.2)% | (6.5)% | (49.2)% | |
| India | (0.6)% | (0.5)% | (13.0)% | |
| Ireland | (3.5)% | (1.4)% | (7.2)% | |
| Other | 9.0 % | 2.7 % | 2.0 % | |
| Deferred tax rate change | (5.2)% | (2.6)% | (5.2)% | |
| Valuation allowance | (4.3)% | 3.9 % | 79.9 % | |
| Withholding taxes | 4.1 % | 1.3 % | 14.3 % | |
| Merger of foreign subsidiaries | — % | — % | (123.5)% | |
| Other foreign items | 9.7 % | 0.5 % | (8.1)% | |
| Effective tax rate | (18.1)% | 22.9 % | (294.4)% | |

During 2016, the Company merged its wholly owned subsidiary, Jai Pharma Limited, into Mylan India. The merger resulted in the recognition of a deferred tax asset of approximately \$150 million for the tax deductible goodwill in excess of the book goodwill with a corresponding benefit to income tax provision for the year ended December 31, 2016.

Valuation Allowance

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. At December 31, 2018, a valuation allowance has been applied to certain deferred tax assets in the amount of \$806.0 million.

When assessing the realizability of deferred tax assets, management considers all available evidence, including historical information, long-term forecasts of future taxable income and possible tax planning strategies. Amounts

recorded for

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valuation allowances can result from a complex series of estimates, assumptions and judgments about future events. Due to the inherent uncertainty involved in making these estimates, assumptions and judgments, actual results could differ materially. Any future increases to the Company's valuation allowances could materially impact the Company's consolidated financial condition and results of operations.

Net Operating Losses

As of December 31, 2018, the Company has U.S. federal net operating loss carry-forwards of \$44.0 million, and U.S. state income tax loss carry-forwards of approximately \$2.80 billion. The Company also has non-U.S. net operating loss carryforwards of approximately \$1.69 billion, of which \$1.39 billion can be carried forward indefinitely, with the remaining \$300.0 million expiring in years 2019 through 2037. Most of the net operating losses have a full valuation allowance. The Company also has \$71.0 million of foreign deductible attributes that can be carried forward indefinitely.

The Company has \$73.4 million of foreign capital loss carry-forwards expiring in 2019 through 2022. A full valuation allowance is recorded against these losses. The Company also has \$211.0 million of U.S. and foreign credit carryovers, expiring in various amounts through 2038.

Tax Examinations

The Company is subject to income taxes and tax audits in many jurisdictions. A certain degree of estimation is thus required in recording the assets and liabilities related to income taxes. Tax audits and examinations can involve complex issues, interpretations, and judgments and the resolution of matters that may span multiple years, particularly if subject to litigation or negotiation.

Although the Company believes that adequate provisions have been made for these uncertain tax positions, the Company's assessment of uncertain tax positions is based on estimates and assumptions that the Company believes are reasonable but the estimates for unrecognized tax benefits and potential tax benefits may not be representative of actual outcomes, and variations from such estimates could materially affect the Company's financial condition, results of operations or cash flows in the period of resolution, settlement or when the statutes of limitations expire.

Mylan is subject to ongoing U.S. Internal Revenue Service ("IRS") examinations and is a voluntary participant in the IRS Compliance Assurance Process ("CAP"), which allows Mylan to work collaboratively with the IRS to identify and review tax matters on an ongoing basis. The years 2015, 2016 and 2017 are open years under examination. The years 2012, 2013 and 2014 have one matter open, and a Tax Court petition has been filed regarding the matter and a trial was held in December 2018. On February 27, 2015, Mylan N.V. acquired Mylan Inc. and Abbott Laboratories' non-U.S. developed markets specialty and branded generics business (collectively, the "EPD Business Acquisition"). In connection with the EPD Business Acquisition, we entered into intercompany transactions with our affiliates that affect our U.S. tax liability. Mylan N.V. is not incorporated in the U.S. and expects to be treated as a non-U.S. corporation for U.S. federal income tax purposes. As part of our ongoing participation and cooperation in the CAP, we have received and responded to various IRS requests for information about, among other matters, the EPD Business Acquisition, including the interest rates used for intercompany loans and our status as a non-U.S. corporation for U.S. federal income tax purposes. As previously disclosed, the IRS may challenge our positions on the EPD Business Acquisition. We remain confident in our positions and, should the IRS choose to challenge our positions, we would vigorously defend our positions through all available channels. If the IRS chooses to challenge our positions, and if the IRS succeeds, we would be subject to significantly greater U.S. tax liability, beginning February 27, 2015, than currently contemplated as a non-U.S. corporation, which would have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or ordinary share price.

The Company's major state taxing jurisdictions remain open from fiscal year 2008 through 2017, with several state audits currently in progress. The Company's major international taxing jurisdictions remain open from 2011 through 2017, some of which are indemnified by Strides Arcolab for tax assessments.

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Tax Court Proceeding

The Company's U.S. federal income tax returns for 2007 through 2011 had been subject to proceedings in U.S. Tax Court involving a dispute with the IRS regarding whether the proceeds received by the Company in connection with the 2008 sale of its rights in nebigolol constituted a capital gain or ordinary income. The Company and the IRS filed a joint stipulation of settled issues with the Tax Court that resolved all issues in this dispute and the Tax Court issued the final order closing the case during 2018.

Accounting for Uncertainty in Income Taxes

The impact of an uncertain tax position that is more likely than not of being sustained upon audit by the relevant taxing authority must be recognized at the largest amount that is more likely than not to be sustained. No portion of an uncertain tax position will be recognized if the position has less than a 50% likelihood of being sustained.

As of December 31, 2018 and 2017, the Company's Consolidated Balance Sheets reflect net liabilities for unrecognized tax benefits of \$96.3 million and \$185.7 million, of which \$96.3 million and \$138.4 million, respectively, would affect the Company's effective tax rate if recognized. Accrued interest and penalties included in the Consolidated Balance Sheets were \$72.6 million and \$90.9 million as of December 31, 2018 and 2017, respectively. For the year ended December 31, 2018, 2017 and 2016, Mylan recognized \$18.3 million of interest income and \$11.1 million and \$6.9 million, respectively, of interest expense related to uncertain tax positions. Interest and penalties related to income taxes are included in the tax provision.

A reconciliation of the unrecognized tax benefits is as follows:

| (In millions) | Year Ended December 31, | | |
|---|-------------------------|---------|---------|
| | 2018 | 2017 | 2016 |
| Unrecognized tax benefit — beginning of year | \$185.7 | \$190.9 | \$174.1 |
| Additions for current year tax positions | — | 4.4 | 2.1 |
| Additions for prior year tax positions | 20.0 | 5.5 | — |
| Reductions for prior year tax positions | (5.8) | (0.8) | (1.8) |
| Settlements | (32.9) | (0.4) | — |
| Reductions due to expirations of statute of limitations | (70.7) | (13.9) | (7.7) |
| Addition due to acquisition | — | — | 24.2 |
| Unrecognized tax benefit — end of year | \$96.3 | \$185.7 | \$190.9 |

The Company believes that it is reasonably possible that the amount of unrecognized tax benefits will decrease in the next twelve months by approximately \$40.0 million, involving federal and state audits and settlements and expirations of certain state, federal, and foreign statutes of limitations. The Company does not anticipate significant increases to the reserve within the next twelve months.

12. Share-Based Incentive Plan

The Company's shareholders have approved the 2003 Long-Term Incentive Plan (as amended, the "2003 Plan"). Under the 2003 Plan, 55,300,000 ordinary shares are reserved for issuance to key employees, consultants, independent contractors and non-employee directors of the Company through a variety of incentive awards, including: stock options, stock appreciation rights ("SAR"), restricted ordinary shares and units, performance awards ("PSU"), other stock-based awards and short-term cash awards. Stock option awards are granted with an exercise price equal to the fair market value of the ordinary shares underlying the options at the date of the grant, generally become exercisable over periods ranging from three to four years, and generally expire in ten years.

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The following table summarizes stock option and SAR (together, “stock awards”) activity:

| | Number of Shares Under Stock Awards | Weighted Average Exercise Price per Share |
|--|---|--|
| Outstanding at December 31, 2015 | 7,732,499 | \$ 31.85 |
| Granted | 876,397 | 45.51 |
| Exercised | (612,477) | 23.13 |
| Forfeited | (296,978) | 50.70 |
| Outstanding at December 31, 2016 | 7,699,441 | \$ 33.38 |
| Granted | 964,475 | 42.48 |
| Exercised | (902,041) | 20.06 |
| Forfeited | (563,191) | 47.36 |
| Outstanding at December 31, 2017 | 7,198,684 | \$ 35.17 |
| Granted | 905,265 | 40.38 |
| Exercised | (820,603) | 21.75 |
| Forfeited | (468,068) | 47.86 |
| Outstanding at December 31, 2018 | 6,815,278 | \$ 36.61 |
| Vested and expected to vest at December 31, 2018 | 6,603,247 | \$ 36.41 |
| Exercisable at December 31, 2018 | 5,134,445 | \$ 34.76 |

As of December 31, 2018, stock awards outstanding, stock awards vested and expected to vest, and stock awards exercisable had average remaining contractual terms of 5.3 years, 5.2 years and 4.2 years, respectively. Also at December 31, 2018, stock awards outstanding, stock awards vested and expected to vest and stock awards exercisable each had aggregate intrinsic values of \$15.9 million.

A summary of the status of the Company’s nonvested restricted ordinary shares and restricted stock unit awards, including PSUs (collectively, “restricted stock awards”) as of December 31, 2017 and the changes during the year ended December 31, 2018 are presented below:

| | Number of Restricted Stock Awards | Weighted Average Grant-Date Fair Value Per Share |
|--------------------------------|--------------------------------------|--|
| Nonvested at December 31, 2017 | 5,964,207 | \$ 41.92 |
| Granted | 1,542,727 | 41.00 |
| Released | (762,561) | 49.11 |
| Forfeited | (351,292) | 43.70 |
| Nonvested at December 31, 2018 | 6,393,081 | \$ 40.75 |

Of the 1,542,727 restricted stock awards granted during the year ended December 31, 2018, 757,433 vest ratably in three years or less and are not subject to market or performance conditions. Of the remaining restricted stock awards granted, 668,878 are subject to market conditions and will cliff vest in three years or less and 116,416 are not subject to market or performance conditions and will cliff vest in one year or less.

As of December 31, 2018, the Company had \$80.6 million of total unrecognized compensation expense, net of estimated forfeitures, related to all of its stock-based awards, which we expect to be recognized over the remaining weighted average vesting period of 1.5 years. The total intrinsic value of stock-based awards exercised and restricted stock awards released during the years ended December 31, 2018 and 2017 was \$46.3 million and \$39.1 million, respectively.

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With respect to options granted under the Company's 2003 Plan, the fair value of each option grant was estimated at the date of grant using the Black-Scholes option pricing model. Black-Scholes utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield and employee exercise behavior. Expected volatilities utilized in the model are based mainly on the implied volatility of the Company's stock price and other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The model incorporates exercise and post-vesting forfeiture assumptions based on an analysis of historical data. The expected lives of the grants are derived from historical and other factors.

The assumptions used for options granted under the 2003 Plan are as follows:

| | Year Ended December 31, | | |
|---|----------------------------|---------|---------|
| | 2018 | 2017 | 2016 |
| Volatility | 35.8% | 33.2% | 38.1% |
| Risk-free interest rate | 2.8% | 2.2% | 1.4% |
| Expected term (years) | 6.5 | 6.4 | 6.3 |
| Forfeiture rate | 5.5% | 5.5% | 5.5% |
| Weighted average grant date fair value per option | \$16.51 | \$15.88 | \$17.90 |

In February 2014, Mylan's Compensation Committee and the independent members of the Board of Directors adopted the One-Time Special Performance-Based Five-Year Realizable Value Incentive Program (the "2014 Program") under the 2003 Plan. Under the 2014 Program, certain key employees received a one-time, performance-based incentive award (the "Awards") either in the form of a grant of SARs or PSUs. The initial Awards were granted in February 2014 and contain a five-year cliff-vesting feature based on the achievement of various performance targets, external market conditions and the employee's continued services. Additional Awards were granted in 2016 and 2017 and are subject to the same performance conditions as the Awards granted in February 2014 and with a service vesting condition of between two and six years. The market condition was met on June 10, 2015. During the year ended December 31, 2018, the Company determined that it was no longer probable that the minimum performance condition would be met and therefore reversed all of the cumulative expense related to the Awards resulting in a reduction in share-based compensation expense of approximately \$70.6 million. In addition, during the year ended December 31, 2018, the Company recorded \$20.0 million of compensation expense as an additional discretionary bonus for a certain group of employees. None of the employees who are eligible for this bonus are named executive officers. As of December 31, 2018, there are approximately 2.6 million Awards outstanding under the 2014 Program, which are expected to be canceled in the first quarter of 2019.

13. Employee Benefit Plans

Defined Benefit Plans

The Company sponsors various defined benefit pension plans in several countries. Benefits provided generally depend on length of service, pay grade and remuneration levels. The Company maintains two fully frozen defined benefit pension plans in the U.S., and employees in the U.S. and Puerto Rico are provided retirement benefits through defined contribution plans rather than through a defined benefit plan.

The Company also sponsors other postretirement benefit plans. There are plans that provide for postretirement supplemental medical coverage. Benefits from these plans are paid to certain employees and their spouses and dependents who meet various minimum age and service requirements. In addition, there are plans that provide for life insurance benefits and postretirement medical coverage for certain officers and management employees.

Accounting for Defined Benefit Pension and Other Postretirement Plans

The Company recognizes on its balance sheet an asset or liability equal to the over- or under-funded benefit obligation of each defined benefit pension and other postretirement plan. Actuarial gains or losses and prior service costs or credits that arise during the period are not recognized as components of net periodic benefit cost, but are recognized, net of tax, as a component of other comprehensive income.

Included in accumulated other comprehensive loss as of December 31, 2018 and 2017 are:

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| (In millions) | Pension Benefits | | Other Postretirement Benefits | |
|---------------------------------------|-------------------|-------------------|-------------------------------|-------------------|
| | December 31, 2018 | December 31, 2017 | December 31, 2018 | December 31, 2017 |
| Unrecognized actuarial (gains) losses | \$(10.3) | \$(8.6) | \$ 1.1 | \$ 2.0 |
| Unrecognized prior service costs | 12.1 | 2.0 | 0.7 | 0.7 |
| Total | \$1.8 | \$(6.6) | \$ 1.8 | \$ 2.7 |

Of the December 31, 2018 amount, the Company expects to recognize approximately \$0.9 million of unrecognized actuarial gains and \$1.0 million of unrecognized prior service costs in net periodic benefit cost during 2019. The unrecognized net actuarial losses exceeded 10% of the higher of the market value of plan assets or the projected benefit obligation at the beginning of the year for certain of the plans, therefore, amortization of such excess has been included in net periodic benefit costs for pension and other postretirement benefits in each of the last three years. The amortization period is the average remaining service period that active employees are expected to receive benefits, unless a plan is mostly inactive in which case the amortization period is the average remaining life expectancy of the plan participants. Unrecognized prior service cost is amortized over the future service periods of those employees who are active at the dates of the plan amendments and who are expected to receive benefits. If all or almost all of a plan's participants are inactive, unrecognized prior service cost is amortized over the remaining life expectancy of those participants. The increase in accumulated other comprehensive income in 2018 relating to pension benefits and other postretirement benefits consists of:

| (In millions) | Pension Benefits | Other Postretirement Benefits |
|--|------------------|-------------------------------|
| Unrecognized actuarial (gain)/loss | \$ (2.1) | \$ (0.6) |
| Amortization of actuarial (gain)/loss | (0.1) | (0.3) |
| Unrecognized prior service costs | 6.6 | — |
| Amortization of prior service costs | (0.4) | — |
| Impact of foreign currency translation | 0.7 | — |
| Net change | \$ 4.7 | \$ (0.9) |

Components of net periodic benefit cost, change in projected benefit obligation, change in plan assets, funded status, fair value of plan assets, assumptions used to determine net periodic benefit cost, funding policy and estimated future benefit payments are summarized below for the Company's pension plans and other postretirement plans.

Net Periodic Benefit Cost

Components of net periodic benefit cost for the years ended December 31, 2018, 2017 and 2016 were as follows:

| (In millions) | Pension Benefits | | | Other Postretirement Benefits | | |
|--|-------------------|-------------------|-------------------|-------------------------------|-------------------|-------------------|
| | December 31, 2018 | December 31, 2017 | December 31, 2016 | December 31, 2018 | December 31, 2017 | December 31, 2016 |
| Service cost | \$19.2 | \$20.1 | \$17.4 | \$0.6 | \$0.7 | \$0.6 |
| Interest cost | 13.0 | 13.6 | 8.2 | 1.5 | 1.6 | 1.3 |
| Expected return on plan assets | (14.4) | (14.3) | (10.9) | — | — | — |
| Plan curtailment, settlement and termination | (0.1) | (1.7) | (2.4) | — | — | — |
| Amortization of prior service costs | 0.3 | 0.2 | 0.3 | — | — | — |
| Recognized net actuarial (gains) losses | (0.1) | 0.3 | 0.8 | 0.2 | 0.4 | 0.3 |
| Net periodic benefit cost | \$17.9 | \$18.2 | \$13.4 | \$2.3 | \$2.7 | \$2.2 |

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Change in Projected Benefit Obligation, Change in Plan Assets and Funded Status

The table below presents components of the change in projected benefit obligation, change in plan assets and funded status at December 31, 2018 and 2017.

| (In millions) | Pension Benefits | | Other Postretirement Benefits | |
|---|------------------|-----------|-------------------------------|----------|
| | 2018 | 2017 | 2018 | 2017 |
| Change in Projected Benefit Obligation | | | | |
| Projected benefit obligation, beginning of year | \$665.2 | \$632.9 | \$35.1 | \$38.0 |
| Service cost | 19.2 | 20.1 | 0.7 | 0.7 |
| Interest cost | 13.0 | 13.6 | 1.3 | 1.6 |
| Participant contributions | 1.0 | 1.0 | 0.2 | 0.2 |
| Transferred liabilities | 16.1 | 0.5 | — | — |
| Plan settlements and terminations | (7.6) | (28.4) | — | — |
| Actuarial losses (gains) | (27.4) | 9.3 | (0.6) | (2.7) |
| Benefits paid | (24.9) | (24.5) | (2.7) | (2.5) |
| Impact of foreign currency translation | (19.2) | 40.7 | — | (0.2) |
| Projected benefit obligation, end of year | \$635.4 | \$665.2 | \$34.0 | \$35.1 |
| Change in Plan Assets | | | | |
| Fair value of plan assets, beginning of year | \$296.1 | \$291.7 | \$— | \$— |
| Actual return on plan assets | (11.0) | 21.7 | — | — |
| Company contributions | 28.9 | 31.5 | 2.5 | 2.3 |
| Participant contributions | 1.0 | 1.0 | 0.2 | 0.2 |
| Transferred assets | 16.1 | 0.5 | — | — |
| Plan settlements | (16.5) | (28.0) | — | — |
| Benefits paid | (24.9) | (24.5) | (2.7) | (2.5) |
| Other | (1.6) | (0.4) | — | — |
| Impact of foreign currency translation | (4.6) | 2.6 | — | — |
| Fair value of plan assets, end of year | 283.5 | 296.1 | — | — |
| Funded status of plans | \$(351.9) | \$(369.1) | \$(34.0) | \$(35.1) |

Net accrued benefit costs for pension plans and other postretirement benefits are reported in the following components of the Company's Consolidated Balance Sheets at December 31, 2018 and 2017:

| (In millions) | Pension Benefits | | Other Postretirement Benefits | |
|---------------------------|-------------------|-------------------|-------------------------------|-------------------|
| | December 31, 2018 | December 31, 2017 | December 31, 2018 | December 31, 2017 |
| Noncurrent assets | \$5.9 | \$6.0 | \$— | \$— |
| Current liabilities | (11.9) | (11.7) | (1.7) | (1.6) |
| Noncurrent liabilities | (345.9) | (363.4) | (32.3) | (33.5) |
| Net accrued benefit costs | \$(351.9) | \$(369.1) | \$(34.0) | \$(35.1) |

The projected benefit obligation is the actuarial present value of benefits attributable to employee service rendered to date, including the effects of estimated future pay increases. The accumulated benefit obligation is the actuarial present value of benefits attributable to employee service rendered to date, but does not include the effects of estimated future pay increases. The accumulated benefit obligation for the Company's pension plans was \$592.5 million and \$598.5 million at December 31, 2018 and 2017, respectively.

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The projected benefit obligation, accumulated benefit obligation and fair value of plan assets for pension plans with an accumulated benefit obligation in excess of the fair value of plan assets at December 31, 2018 and 2017 were as follows:

| (In millions) | December 31, | |
|---|--------------|---------|
| | 2018 | 2017 |
| Plans with accumulated benefit obligation in excess of plan assets: | | |
| Projected benefit obligation | \$502.9 | \$530.1 |
| Accumulated benefit obligation | 483.1 | 506.0 |
| Fair value of plan assets | 154.8 | 164.8 |
| Fair Value of Plan Assets | | |

The Company measures the fair value of plan assets based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are based on a three-tier hierarchy described in Note 8 Financial Instruments and Risk Management. The table below presents total plan assets by investment category as of December 31, 2018 and 2017 and the classification of each investment category within the fair value hierarchy with respect to the inputs used to measure fair value:

| (In millions) | December 31, 2018 | | | |
|--|-------------------|---------|---------|---------|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash and cash equivalents | \$3.5 | \$0.4 | \$— | \$3.9 |
| Equity securities | 58.5 | 66.0 | — | 124.5 |
| Fixed income securities | 65.4 | 58.4 | — | 123.8 |
| Assets held by insurance companies and other | 0.1 | 7.2 | 24.0 | 31.3 |
| Total | \$127.5 | \$132.0 | \$24.0 | \$283.5 |

| (In millions) | December 31, 2017 | | | |
|--|-------------------|---------|---------|---------|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash and cash equivalents | \$2.5 | \$0.3 | \$— | \$2.8 |
| Equity securities | 65.2 | 71.8 | — | 137.0 |
| Fixed income securities | 45.2 | 57.6 | — | 102.8 |
| Assets held by insurance companies and other | 10.4 | 23.9 | 19.2 | 53.5 |
| Total | \$123.3 | \$153.6 | \$19.2 | \$296.1 |

Risk tolerance on invested pension plan assets is established through careful consideration of plan liabilities, plan funded status and corporate financial condition. Investment risk is measured and monitored on an ongoing basis through annual liability measures, periodic asset/liability studies and investment portfolio reviews. The Company's investment strategy is to maintain, where possible, a diversified investment portfolio across several asset classes that, when combined with the Company's contributions to the plans, will ensure that required benefit obligations are met.

Assumptions
The following weighted average assumptions were used to determine the benefit obligations for the Company's defined benefit pension and other postretirement plans as of December 31, 2018 and 2017:

| | Pension Benefits | | Other Postretirement Benefits | |
|--------------------------------|------------------|------|-------------------------------|------|
| | 2018 | 2017 | 2018 | 2017 |
| Discount rate | 2.3% | 2.0% | 4.3% | 3.7% |
| Expected return on plan assets | 4.9% | 4.9% | —% | —% |
| Rate of compensation increase | 2.9% | 2.8% | —% | —% |

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The following weighted average assumptions were used to determine the net periodic benefit cost for the Company's defined benefit pension and other postretirement benefit plans for the three years in the period ended December 31, 2018:

| | Pension Benefits | | | Other Postretirement Benefits | | |
|--------------------------------|------------------|------|------|-------------------------------|------|------|
| | 2018 | 2017 | 2016 | 2018 | 2017 | 2016 |
| Discount rate | 2.0% | 2.2% | 2.1% | 3.7% | 4.2% | 4.2% |
| Expected return on plan assets | 4.9% | 5.0% | 4.9% | — % | — % | — % |
| Rate of compensation increase | 2.9% | 2.8% | 3.2% | — % | — % | — % |

The assumptions for each plan are reviewed on an annual basis. The discount rate reflects the current rate at which the pension and other benefit liabilities could be effectively settled at the measurement date. In setting the discount rates, we utilize comparable corporate bond indices as an indication of interest rate movements and levels. Corporate bond indices were selected based on individual plan census data and duration. The expected return on plan assets was determined using historical market returns and long-term historical relationships between equities and fixed income securities. The Company compares the expected return on plan assets assumption to actual historic returns to ensure reasonableness. Current market factors such as inflation and interest rates are also evaluated.

The weighted-average healthcare cost trend rate used for 2018 was 7.5% declining to a projected 5.0% in the year 2022. For 2019, the assumed weighted-average healthcare cost trend rate used will be 5.6% declining to a projected 4.5% in the year 2023. In selecting rates for current and long-term healthcare cost assumptions, the Company takes into consideration a number of factors including the Company's actual healthcare cost increases, the design of the Company's benefit programs, the demographics of the Company's active and retiree populations and external expectations of future medical cost inflation rates. If these 2019 healthcare cost trend rates were increased or decreased by one percentage point per year, such increase or decrease would have the following effects:

| (In millions) | Increase | Decrease |
|--|----------|-----------|
| Increase (decrease) in the aggregate of service and interest cost components of annual expense | \$ 0.1 | \$ (0.1) |
| Increase (decrease) in the projected benefit obligation | 1.2 | (1.0) |

Estimated Future Benefit Payments

The Company's funding policy for its funded pension plans is based upon local statutory requirements. The Company's funding policy is subject to certain statutory regulations with respect to annual minimum and maximum company contributions. Plan benefits for the nonqualified plans are paid as they come due.

Estimated benefit payments over the next ten years for the Company's pension plans and retiree health plan are as follows:

| (In millions) | Pension Benefits | Other Postretirement Benefits |
|---------------|------------------|-------------------------------|
| 2019 | \$ 32.0 | \$ 1.7 |
| 2020 | 34.2 | 1.7 |
| 2021 | 35.7 | 2.0 |
| 2022 | 34.0 | 2.3 |
| 2023 | 36.4 | 2.2 |
| Thereafter | 192.1 | 11.6 |
| Total | \$ 364.4 | \$ 21.5 |

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Defined Contribution Plans

The Company sponsors defined contribution plans covering its employees in the U.S. and Puerto Rico, as well as certain employees in a number of countries outside the U.S. The Company's domestic defined contribution plans consist primarily of a 401(k) retirement plan with a profit sharing component for non-union represented employees (the "Profit Sharing 401(k) Plan") and a 401(k) retirement plan for union-represented employees. Profit sharing contributions are made at the discretion of the Board of Directors. The Company's non-domestic plans vary in form depending on local legal requirements. The Company's contributions are based upon employee contributions, service hours, or pre-determined amounts depending upon the plan. Obligations for contributions to defined contribution plans are recognized as expense in the Consolidated Statements of Operations when they are earned.

The Company adopted a 401(k) Restoration Plan (the "Restoration Plan"), which permits employees who earn compensation in excess of the limits imposed by Section 401(a)(17) of the Code to (i) defer a portion of base salary and bonus compensation, (ii) be credited with a Company matching contribution in respect of deferrals under the Restoration Plan, and (iii) be credited with Company non-elective contributions (to the extent so made by the Company), in each case, to the extent that participants otherwise would be able to defer or be credited with such amounts, as applicable, under the Profit Sharing 401(k) Plan if not for the limits on contributions and deferrals imposed by the Code.

The Company adopted an Income Deferral Plan, which permits certain management or highly compensated employees who are designated by the plan administrator to participate in the Income Deferral Plan to elect to defer up to 50% of base salary and up to 100% of bonus compensation, in each case, in addition to any amounts that may be deferred by such participants under the Profit Sharing 401(k) Plan and the Restoration Plan. In addition, under the Income Deferral Plan, eligible participants may be granted employee deferral awards, which awards will be subject to the terms and conditions (including vesting) as determined by the plan administrator at the time such awards are granted.

Total employer contributions to defined contribution plans were approximately \$85.2 million, \$95.9 million and \$95.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Other Benefit Arrangements

The Company participated in a multi-employer pension plan under previous collective bargaining agreements. The PACE Industry Union-Management Pension Fund (the "Plan") provides defined benefits to certain retirees and certain production and maintenance employees at the Company's manufacturing plant in Morgantown, West Virginia who were covered by the previous collective bargaining agreements. Pursuant to a collective bargaining agreement entered into on April 16, 2012, the Company withdrew from the Plan effective May 10, 2012. In 2013, the Plan trustee notified the Company that its withdrawal liability was approximately \$27.3 million, which was accrued by the Company in 2013. The withdrawal liability is being paid over a period of approximately nine years; payments began in March 2014. The withdrawal liability was approximately \$15.1 million and \$18.1 million at December 31, 2018 and 2017, respectively. The Employee Identification Number for the Plan is 11-6166763.

14. Segment Information

Mylan reports segment information on a geographic basis. This approach reflects the company's focus on bringing its broad and diversified portfolio of generic, branded generic, brand-name and OTC products to people in markets everywhere. Our North America segment comprises our operations in the U.S. and Canada. Our Europe segment encompasses our operations in 35 countries, including France, Italy, Germany, the U.K. and Spain. Our Rest of World segment reflects our operations in more than 120 countries, including Japan, Australia, China, Brazil, Russia, India, South Africa and certain markets in the Middle East and Southeast Asia.

The Company's chief operating decision maker is the Chief Executive Officer, who evaluates the performance of its segments based on total revenues and segment profitability. Segment profitability represents segment gross profit less direct R&D and direct SG&A. Certain general and administrative and R&D expenses not allocated to the segments, including certain special items, net charges for litigation settlements and other contingencies, amortization of intangible assets, impairment charges and other expenses not directly attributable to the segments are reported separately or outside of segment profitability. Items below the earnings from operations line on the Company's

Consolidated Statements of Operations are not presented by segment, since they are excluded from the measure of segment profitability. The Company has revised segment profitability for Rest of World to conform with the current presentation by reclassifying approximately \$78.2 million of net gains to litigation settlements and other contingencies for the year ended December 31, 2017. The Company does not report depreciation expense, total assets and capital expenditures by segment, as such information is not used by the chief operating decision maker.

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The accounting policies of the segments are the same as those described in Note 2 Summary of Significant Accounting Policies. Intersegment revenues are accounted for at current market values and are eliminated at the consolidated level.

Presented in the table below is segment information for the periods identified and a reconciliation of segment information to total consolidated information.

| (In millions) | North America | Europe | Rest of World | Corporate / Other | Consolidated |
|---|------------------|------------|------------------|----------------------|--------------|
| Year Ended December 31, 2018 | | | | | |
| Net sales | \$4,095.6 | \$4,157.3 | \$3,015.8 | \$— | \$ 11,268.7 |
| Other revenue | 112.4 | 27.1 | 25.7 | — | 165.2 |
| Intersegment revenue | 85.2 | 107.8 | 343.9 | (536.9) | — |
| Total | \$4,293.2 | \$4,292.2 | \$3,385.4 | \$(536.9) | \$ 11,433.9 |
| Segment profitability | \$ 1,838.4 | \$ 1,089.5 | \$ 692.0 | \$— | \$ 3,619.9 |
| Intangible asset amortization expense | | | | | (1,606.4) |
| Intangible asset impairment charges | | | | | (224.0) |
| Globally managed research and development costs | | | | | (250.3) |
| Corporate costs and special items | | | | | (683.1) |
| Litigation settlements & other contingencies | | | | | 49.5 |
| Earnings from operations | | | | | \$ 905.6 |
| | North America | Europe | Rest of World | Corporate / Other | Consolidated |
| Year Ended December 31, 2017 | | | | | |
| Net sales | \$4,969.6 | \$3,958.3 | \$2,832.1 | \$— | \$ 11,760.0 |
| Other revenue | 86.5 | 36.5 | 24.7 | — | 147.7 |
| Intersegment revenue | 74.6 | 112.4 | 379.2 | (566.2) | — |
| Total | \$5,130.7 | \$4,107.2 | \$3,236.0 | \$(566.2) | \$ 11,907.7 |
| Segment profitability | \$2,497.1 | \$ 1,082.8 | \$ 572.7 | \$— | \$ 4,152.6 |
| Intangible asset amortization expense | | | | | (1,437.4) |
| Intangible asset impairment charges | | | | | (80.8) |
| Globally managed research and development costs | | | | | (356.4) |
| Corporate costs and special items | | | | | (853.9) |
| Litigation settlements & other contingencies | | | | | 13.1 |
| Earnings from operations | | | | | \$ 1,437.2 |

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| | North America | Europe | Rest of World | Corporate / Other | Consolidated |
|---|------------------|-----------|------------------|----------------------|--------------|
| Year Ended December 31, 2016 | | | | | |
| Net sales | \$5,629.5 | \$2,953.8 | \$2,383.8 | \$— | \$ 10,967.1 |
| Other revenue | 88.4 | 12.6 | 8.8 | — | 109.8 |
| Intersegment revenue | 45.4 | 106.3 | 407.6 | (559.3) | — |
| Total | \$5,763.3 | \$3,072.7 | \$2,800.2 | \$(559.3) | \$ 11,076.9 |
| Segment profitability | \$2,921.2 | \$669.4 | \$423.5 | \$— | \$4,014.1 |
| Intangible asset amortization expense | | | | | (1,195.3) |
| Intangible asset impairment charges | | | | | (68.3) |
| Globally managed research and development costs | | | | | (423.7) |
| Corporate costs and special items | | | | | (955.1) |
| Litigation settlements & other contingencies | | | | | (672.5) |
| Earnings from operations | | | | | \$ 699.2 |

The following table represents the percentage of consolidated net sales to Mylan's major customers during the years ended December 31, 2018, 2017, and 2016:

| | Percentage of Consolidated Net Sales | | |
|-------------------------------|--|------|------|
| | 2018 | 2017 | 2016 |
| McKesson Corporation | 12 % | 13 % | 16 % |
| AmerisourceBergen Corporation | 8 % | 8 % | 14 % |
| Cardinal Health, Inc. | 8 % | 10 % | 11 % |

Sales by Country Information

Net sales by country are presented on the basis of geographic location of our subsidiaries:

| | Year Ended December 31, | | |
|--------------------------------|-------------------------|------------|------------|
| (In millions) | 2018 | 2017 | 2016 |
| United States | \$3,865.2 | \$4,683.7 | \$5,385.6 |
| India | 1,164.8 | 1,082.6 | 985.8 |
| The Netherlands ⁽¹⁾ | 132.2 | 117.5 | 88.3 |
| Other countries ⁽²⁾ | 6,106.5 | 5,876.2 | 4,507.4 |
| | \$11,268.7 | \$11,760.0 | \$10,967.1 |

⁽¹⁾ Mylan N.V. has its corporate seat in the Netherlands.

⁽²⁾ No other country's net sales represents more than 10% of consolidated net sales for the years ended December 31, 2018, 2017 and 2016, respectively.

15. CommitmentsOperating Leases

The Company leases certain property under various operating lease arrangements. These leases generally provide the Company with the option to renew the lease at the end of the lease term. For the years ended December 31, 2018, 2017 and 2016, the Company had operating lease expense of approximately \$78.9 million, \$83.8 million and \$70.8 million, respectively.

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Future minimum lease payments under operating lease commitments are as follows:

(In millions)

| | |
|--------------|---------|
| December 31, | |
| 2019 | \$73.7 |
| 2020 | 54.7 |
| 2021 | 40.2 |
| 2022 | 28.5 |
| 2023 | 18.3 |
| Thereafter | 54.2 |
| | \$269.6 |

Other Commitments

The Company has also entered into employment and other agreements with certain executives and other employees that provide for compensation, retirement and certain other benefits. These agreements provide for severance payments under certain circumstances. Additionally, the Company has split-dollar life insurance agreements with certain retired executives.

In the normal course of business, Mylan periodically enters into employment, legal settlement and other agreements which incorporate indemnification provisions. While the maximum amount to which Mylan may be exposed under such agreements cannot be reasonably estimated, the Company maintains insurance coverage, which management believes will effectively mitigate the Company's obligations under these indemnification provisions. No amounts have been recorded in the Consolidated Financial Statements with respect to the Company's obligations under such agreements.

16. Subsidiary Guarantors

The following tables present condensed consolidating financial information for (a) Mylan N.V., the issuer of the 2.500% Senior Notes due 2019, 3.750% Senior Notes due 2020, 3.150% Senior Notes due 2021, 3.950% Senior Notes due 2026 and 5.250% Senior Notes due 2046 (collectively, the "Mylan N.V. Senior Notes"), which are guaranteed on a senior unsecured basis by Mylan Inc.; (b) Mylan Inc., the issuer of the 3.125% Senior Notes due 2023, 4.200% Senior Notes due 2023, 4.550% Senior Notes due 2028, 5.400% Senior Notes due 2043 and 5.200% Senior Notes due 2048 (collectively, the "Mylan Inc. Senior Notes"), which are guaranteed on a senior unsecured basis by Mylan N.V.; and (c) all other subsidiaries of the Company on a combined basis, none of which guarantee the Mylan N.V. Senior Notes or guarantee the Mylan Inc. Senior Notes ("Non-Guarantor Subsidiaries"). The consolidating adjustments primarily relate to eliminations of investments in subsidiaries and intercompany balances and transactions. The condensed consolidating financial statements present investments in subsidiaries using the equity method of accounting.

The following financial information presents the related Condensed Consolidating Balance Sheets as of December 31, 2018 and 2017 and the related Condensed Consolidating Statements of Operations, Condensed Consolidating Statements of Comprehensive Earnings and Condensed Consolidating Statements of Cash Flows for each of the three years in the period ended December 31, 2018. This condensed consolidating financial information has been prepared and presented in accordance with SEC Regulation S-X Rule 3-10 "Financial Statements of Guarantors and Issuers of Guaranteed Securities Registered or Being Registered."

The Company has revised its consolidating balance sheet as previously presented in the 2017 Annual Report on Form 10-K to appropriately present intercompany activity relating to certain subsidiaries which were included in the Mylan Inc. column. The Company overstated the line items investment in subsidiaries and total equity within the Mylan Inc. column with a corresponding offset to the elimination column. Specifically, the balance sheet caption investment in subsidiaries has been revised from the previously reported amount of \$15.3 billion as of December 31, 2017 to \$13.7 billion with an offset to total equity. There is no impact to the consolidated financial statements of Mylan N.V. as previously filed in the 2017 Annual Report on Form 10-K.

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CONDENSED CONSOLIDATING BALANCE SHEET

As of December 31, 2018

| (In millions) | Mylan N.V. | Mylan Inc. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---------------|---------------|---------------------------|-------------------------------|---------------|--------------|
| ASSETS | | | | | | |
| Assets | | | | | | |
| Current assets: | | | | | | |
| Cash and cash equivalents | \$— | \$18.2 | \$ | —\$ 369.9 | \$— | \$ 388.1 |
| Accounts receivable, net | — | 24.3 | — | 2,856.7 | — | 2,881.0 |
| Inventories | — | — | — | 2,580.2 | — | 2,580.2 |
| Intercompany receivables | 342.9 | 518.7 | — | 13,107.1 | (13,968.7) | — |
| Prepaid expenses and other current assets | 5.6 | 71.3 | — | 441.5 | — | 518.4 |
| Total current assets | 348.5 | 632.5 | — | 19,355.4 | (13,968.7) | 6,367.7 |
| Property, plant and equipment, net | — | 259.7 | — | 1,910.5 | — | 2,170.2 |
| Investments in subsidiaries | 18,995.9 | 13,129.5 | — | — | (32,125.4) | — |
| Intercompany notes and interest receivable | 6,287.4 | 10,732.6 | — | 2,519.8 | (19,539.8) | — |
| Intangible assets, net | — | — | — | 13,664.6 | — | 13,664.6 |
| Goodwill | — | 17.1 | — | 9,730.7 | — | 9,747.8 |
| Other assets | 0.3 | 68.9 | — | 715.4 | — | 784.6 |
| Total assets | \$25,632.1 | \$24,840.3 | \$ | —\$ 47,896.4 | \$(65,633.9) | \$ 32,734.9 |
| LIABILITIES AND EQUITY | | | | | | |
| Liabilities | | | | | | |
| Current liabilities: | | | | | | |
| Accounts payable | \$— | \$70.6 | \$ | —\$ 1,546.4 | \$— | \$ 1,617.0 |
| Short-term borrowings | — | — | — | 1.9 | — | 1.9 |
| Income taxes payable | — | — | — | 121.5 | — | 121.5 |
| Current portion of long-term debt and other long-term obligations | 649.0 | 0.2 | — | 50.6 | — | 699.8 |
| Intercompany payables | 1,618.8 | 12,326.4 | — | 23.5 | (13,968.7) | — |
| Other current liabilities | 21.0 | 216.0 | — | 1,910.6 | — | 2,147.6 |
| Total current liabilities | 2,288.8 | 12,613.2 | — | 3,654.5 | (13,968.7) | 4,587.8 |
| Long-term debt | 9,370.1 | 3,786.2 | — | 4.9 | — | 13,161.2 |
| Intercompany notes payable | 1,806.1 | 3,094.2 | — | 14,639.5 | (19,539.8) | — |
| Other long-term obligations | — | 48.6 | — | 2,770.2 | — | 2,818.8 |
| Total liabilities | 13,465.0 | 19,542.2 | — | 21,069.1 | (33,508.5) | 20,567.8 |
| Total equity | 12,167.1 | 5,298.1 | — | 26,827.3 | (32,125.4) | 12,167.1 |
| Total liabilities and equity | \$25,632.1 | \$24,840.3 | \$ | —\$ 47,896.4 | \$(65,633.9) | \$ 32,734.9 |

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CONDENSED CONSOLIDATING BALANCE SHEET

As of December 31, 2017

| (In millions) | Mylan N.V. | Mylan Inc. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---------------|---------------|---------------------------|-------------------------------|---------------|--------------|
| ASSETS | | | | | | |
| Assets | | | | | | |
| Current assets: | | | | | | |
| Cash and cash equivalents | \$— | \$0.2 | \$ | —\$ 291.9 | \$— | \$ 292.1 |
| Accounts receivable, net | — | 1.0 | — | 3,611.4 | — | 3,612.4 |
| Inventories | — | — | — | 2,542.7 | — | 2,542.7 |
| Intercompany receivables | 317.2 | 462.1 | — | 11,828.5 | (12,607.8) | — |
| Prepaid expenses and other current assets | 5.6 | 171.1 | — | 589.4 | — | 766.1 |
| Total current assets | 322.8 | 634.4 | — | 18,863.9 | (12,607.8) | 7,213.3 |
| Property, plant and equipment, net | — | 294.1 | — | 2,045.0 | — | 2,339.1 |
| Investments in subsidiaries | 19,736.5 | 13,683.3 | — | — | (33,419.8) | — |
| Intercompany notes and interest receivable | 7,822.6 | 10,271.2 | — | 2,186.3 | (20,280.1) | — |
| Intangible assets, net | — | — | — | 15,245.8 | — | 15,245.8 |
| Goodwill | — | 17.1 | — | 10,188.6 | — | 10,205.7 |
| Other assets | 4.9 | 56.5 | — | 741.0 | — | 802.4 |
| Total assets | \$27,886.8 | \$24,956.6 | \$ | —\$ 49,270.6 | \$(66,307.7) | \$ 35,806.3 |
| LIABILITIES AND EQUITY | | | | | | |
| Liabilities | | | | | | |
| Current liabilities: | | | | | | |
| Accounts payable | \$— | \$45.3 | \$ | —\$ 1,407.2 | \$— | \$ 1,452.5 |
| Short-term borrowings | — | — | — | 46.5 | — | 46.5 |
| Income taxes payable | — | — | — | 112.9 | — | 112.9 |
| Current portion of long-term debt and other long-term obligations | 1,097.8 | 649.1 | — | 62.0 | — | 1,808.9 |
| Intercompany payables | 664.7 | 11,911.5 | — | 31.6 | (12,607.8) | — |
| Other current liabilities | 35.5 | 397.0 | — | 2,532.0 | — | 2,964.5 |
| Total current liabilities | 1,798.0 | 13,002.9 | — | 4,192.2 | (12,607.8) | 6,385.3 |
| Long-term debt | 10,614.3 | 2,244.5 | — | 6.5 | — | 12,865.3 |
| Intercompany notes payable | 2,166.9 | 3,312.7 | — | 14,800.5 | (20,280.1) | — |
| Other long-term obligations | — | 57.3 | — | 3,190.8 | — | 3,248.1 |
| Total liabilities | 14,579.2 | 18,617.4 | — | 22,190.0 | (32,887.9) | 22,498.7 |
| Total equity | 13,307.6 | 6,339.2 | — | 27,080.6 | (33,419.8) | 13,307.6 |
| Total liabilities and equity | \$27,886.8 | \$24,956.6 | \$ | —\$ 49,270.6 | \$(66,307.7) | \$ 35,806.3 |

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CONDENSED CONSOLIDATING STATEMENT OF OPERATIONS

Year Ended December 31, 2018

| (In millions) | Mylan N.V. | Mylan Inc. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|--|---------------|---------------|---------------------------|-------------------------------|--------------|--------------|
| Revenues: | | | | | | |
| Net sales | \$— | \$— | \$ | —\$ 11,268.7 | \$ — | \$ 11,268.7 |
| Other revenues | — | — | — | 165.2 | — | 165.2 |
| Total revenues | — | — | — | 11,433.9 | — | 11,433.9 |
| Cost of sales | — | — | — | 7,432.3 | — | 7,432.3 |
| Gross profit | — | — | — | 4,001.6 | — | 4,001.6 |
| Operating expenses: | | | | | | |
| Research and development | — | — | — | 704.5 | — | 704.5 |
| Selling, general and administrative | 40.7 | 517.3 | — | 1,883.0 | — | 2,441.0 |
| Litigation settlements and other contingencies, net | — | 7.1 | — | (56.6 |) — | (49.5) |
| Total operating expenses | 40.7 | 524.4 | — | 2,530.9 | — | 3,096.0 |
| (Losses) earnings from operations | (40.7) | (524.4) | — | 1,470.7 | — | 905.6 |
| Interest expense | 349.0 | 154.6 | — | 38.7 | — | 542.3 |
| Other (income) expense, net | (316.4) | (273.3) | — | 654.6 | — | 64.9 |
| (Losses) earnings before income taxes | (73.3) | (405.7) | — | 777.4 | — | 298.4 |
| Income tax (benefit) provision | (28.7) | (27.4) | — | 2.0 | — | (54.1) |
| Earnings of equity interest subsidiaries | 397.1 | 328.8 | — | — | (725.9) | — |
| Net earnings (loss) | \$352.5 | \$(49.5) | \$ | —\$ 775.4 | \$ (725.9) | \$ 352.5 |

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CONDENSED CONSOLIDATING STATEMENT OF OPERATIONS

Year Ended December 31, 2017

| (In millions) | Mylan N.V. | Mylan Inc. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|--|---------------|---------------|---------------------------|-------------------------------|---------------|--------------|
| Revenues: | | | | | | |
| Net sales | \$— | \$— | \$ | —\$ 11,760.0 | \$— | \$ 11,760.0 |
| Other revenues | — | — | — | 147.7 | — | 147.7 |
| Total revenues | — | — | — | 11,907.7 | — | 11,907.7 |
| Cost of sales | — | — | — | 7,124.6 | — | 7,124.6 |
| Gross profit | — | — | — | 4,783.1 | — | 4,783.1 |
| Operating expenses: | | | | | | |
| Research and development | — | — | — | 783.3 | — | 783.3 |
| Selling, general and administrative | 45.5 | 650.9 | — | 1,879.3 | — | 2,575.7 |
| Litigation settlements and other contingencies, net | — | 17.0 | — | (30.1 |) — | (13.1) |
| Total operating expenses | 45.5 | 667.9 | — | 2,632.5 | — | 3,345.9 |
| (Losses) earnings from operations | (45.5) | (667.9) | — | 2,150.6 | — | 1,437.2 |
| Interest expense | 378.0 | 104.1 | — | 52.5 | — | 534.6 |
| Other (income) expense, net | (484.9) | (264.6) | — | 749.1 | — | (0.4) |
| Earnings (losses) before income taxes and noncontrolling interest | 61.4 | (507.4) | — | 1,349.0 | — | 903.0 |
| Income tax (benefit) provision | (21.1) | (14.0) | — | 242.1 | — | 207.0 |
| Earnings of equity interest subsidiaries | 613.5 | 886.4 | — | — | (1,499.9) | — |
| Net earnings | \$696.0 | \$393.0 | \$ | —\$ 1,106.9 | \$ (1,499.9) | \$ 696.0 |

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CONDENSED CONSOLIDATING STATEMENT OF OPERATIONS

Year Ended December 31, 2016

| (In millions) | Mylan N.V. | Mylan Inc. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|--|---------------|---------------|---------------------------|-------------------------------|---------------|--------------|
| Revenues: | | | | | | |
| Net sales | \$— | \$— | \$ | —\$ 10,967.1 | \$— | \$ 10,967.1 |
| Other revenues | — | — | — | 109.8 | — | 109.8 |
| Total revenues | — | — | — | 11,076.9 | — | 11,076.9 |
| Cost of sales | — | — | — | 6,379.9 | — | 6,379.9 |
| Gross profit | — | — | — | 4,697.0 | — | 4,697.0 |
| Operating expenses: | | | | | | |
| Research and development | — | — | — | 826.8 | — | 826.8 |
| Selling, general and administrative | 71.6 | 664.1 | — | 1,762.8 | — | 2,498.5 |
| Litigation settlements and other contingencies, net | — | — | — | 672.5 | — | 672.5 |
| Total operating expenses | 71.6 | 664.1 | — | 3,262.1 | — | 3,997.8 |
| (Losses) earnings from operations | (71.6) | (664.1) | — | 1,434.9 | — | 699.2 |
| Interest expense | 198.4 | 161.3 | — | 95.1 | — | 454.8 |
| Other (income) expense, net | (55.6) | (193.2) | — | 371.5 | — | 122.7 |
| (Losses) earnings before income taxes and noncontrolling interest | (214.4) | (632.2) | — | 968.3 | — | 121.7 |
| Income tax benefit | (19.5) | (18.2) | — | (320.6) | — | (358.3) |
| Earnings of equity interest subsidiaries | 674.9 | 1,360.2 | — | — | (2,035.1) | — |
| Net earnings | \$480.0 | \$746.2 | \$ | —\$ 1,288.9 | \$ (2,035.1) | \$ 480.0 |

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CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE EARNINGS

Year Ended December 31, 2018

| (In millions) | Mylan N.V. | Mylan Inc. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---------------|---------------|---------------------------|-------------------------------|--------------|--------------|
| Net earnings (loss) | \$352.5 | \$(49.5) | \$ — | \$ 775.4 | \$(725.9) | \$ 352.5 |
| Other comprehensive (loss) earnings, before tax: | | | | | | |
| Foreign currency translation adjustment | (1,125.2) | — | — | (1,125.2) | 1,125.2 | (1,125.2) |
| Change in unrecognized gain and prior service cost related to defined benefit plans | (3.8) | 0.6 | — | (4.4) | 3.8 | (3.8) |
| Net unrecognized (loss) gain on derivatives in cash flow hedging relationships | (79.2) | 7.7 | — | (86.9) | 79.2 | (79.2) |
| Net unrecognized gain on derivatives in net investment hedging relationships | 111.6 | 11.6 | — | — | (11.6) | 111.6 |
| Net unrealized loss on marketable securities | (0.1) | — | — | (0.1) | 0.1 | (0.1) |
| Other comprehensive (loss) earnings, before tax | (1,096.7) | 19.9 | — | (1,216.6) | 1,196.7 | (1,096.7) |
| Income tax benefit | (24.1) | (4.7) | — | (19.4) | 24.1 | (24.1) |
| Other comprehensive (loss) earnings, net of tax | (1,072.6) | 24.6 | — | (1,197.2) | 1,172.6 | (1,072.6) |
| Comprehensive loss | \$(720.1) | \$(24.9) | \$ — | \$(421.8) | \$ 446.7 | \$(720.1) |

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CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE EARNINGS

Year Ended December 31, 2017

| (In millions) | Mylan N.V. | Mylan Inc. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|--|---------------|---------------|---------------------------|-------------------------------|--------------|--------------|
| Net earnings | \$696.0 | \$393.0 | \$ — | \$ 1,106.9 | \$(1,499.9) | \$ 696.0 |
| Other comprehensive earnings, before tax: | | | | | | |
| Foreign currency translation adjustment | 2,103.9 | — | — | 2,103.9 | (2,103.9) | 2,103.9 |
| Change in unrecognized gain and prior service cost related to defined benefit plans | 3.8 | 3.0 | — | 0.8 | (3.8) | 3.8 |
| Net unrecognized gain on derivatives | 52.7 | 7.3 | — | 45.4 | (52.7) | 52.7 |
| Net unrecognized loss on derivatives in net investment hedging relationships | (238.4) | — | — | — | — | (238.4) |
| Net unrealized loss on marketable securities | (6.7) | (6.4) | — | (0.3) | 6.7 | (6.7) |
| Other comprehensive earnings, before tax | 1,915.3 | 3.9 | — | 2,149.8 | (2,153.7) | 1,915.3 |
| Income tax provision (benefit) | 12.8 | (1.6) | — | 14.4 | (12.8) | 12.8 |
| Other comprehensive earnings, net of tax | 1,902.5 | 5.5 | — | 2,135.4 | (2,140.9) | 1,902.5 |
| Comprehensive earnings | \$2,598.5 | \$398.5 | \$ — | \$ 3,242.3 | \$(3,640.8) | \$ 2,598.5 |

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CONDENSED CONSOLIDATING STATEMENT OF COMPREHENSIVE EARNINGS

Year Ended December 31, 2016

| (In millions) | Mylan N.V. | Mylan Inc. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---------------|---------------|---------------------------|-------------------------------|--------------|--------------|
| Net earnings | \$480.0 | \$746.2 | \$ — | \$ 1,288.9 | \$(2,035.1) | \$ 480.0 |
| Other comprehensive loss, before tax: | | | | | | |
| Foreign currency translation adjustment | (507.4) | — | — | (507.4) | 507.4 | (507.4) |
| Change in unrecognized gain (loss) and prior service cost related to defined benefit plans | 21.4 | (1.1) | — | 22.5 | (21.4) | 21.4 |
| Net unrecognized (loss) gain on derivatives | (31.2) | (47.7) | — | 16.5 | 31.2 | (31.2) |
| Net unrecognized loss on derivatives in net investment hedging relationships | (1.8) | — | — | (1.8) | 1.8 | (1.8) |
| Net unrealized gain on marketable securities | 24.6 | 24.6 | — | — | (24.6) | 24.6 |
| Other comprehensive loss, before tax | (494.4) | (24.2) | — | (470.2) | 494.4 | (494.4) |
| Income tax provision (benefit) | 5.0 | (9.1) | — | 4.1 | 5.0 | 5.0 |
| Other comprehensive loss, net of tax | (499.4) | (15.1) | — | (474.3) | 489.4 | (499.4) |
| Comprehensive (loss) earnings | \$(19.4) | \$731.1 | \$ — | \$ 814.6 | \$(1,545.7) | \$(19.4) |

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CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS

Year Ended December 31, 2018

| (In millions) | Mylan N.V. | Mylan Inc. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---------------|-------------|---------------------------|-------------------------------|--------------|--------------|
| Cash flows from operating activities: | | | | | | |
| Net cash (used in) provided by operating activities | \$(230.4) | \$(1,551.7) | \$ — | —\$ 4,123.8 | \$ — | \$ 2,341.7 |
| Cash flows from investing activities: | | | | | | |
| Capital expenditures | — | (28.6) | — | (223.5) | — | (252.1) |
| Cash paid for acquisitions, net of cash acquired | — | — | — | (65.9) | — | (65.9) |
| Proceeds from sale of assets and subsidiaries | — | — | — | 29.3 | — | 29.3 |
| Purchase of marketable securities | — | — | — | (63.4) | — | (63.4) |
| Proceeds from the sale of marketable securities | — | 36.3 | — | 48.9 | — | 85.2 |
| Investments in affiliates | — | (28.8) | — | — | 28.8 | — |
| Dividends from affiliates | 118.6 | — | — | — | (118.6) | — |
| Loans to affiliates | (492.2) | — | — | (5,687.8) | 6,180.0 | — |
| Repayments of loans from affiliates | 2,615.4 | — | — | 4,066.8 | (6,682.2) | — |
| Payments for product rights and other, net | — | (0.5) | — | (943.0) | — | (943.5) |
| Net cash provided by (used in) investing activities | 2,241.8 | (21.6) | — | (2,838.6) | (592.0) | (1,210.4) |
| Cash flows from financing activities: | | | | | | |
| Payments of financing fees | (0.6) | (20.8) | — | — | — | (21.4) |
| Purchase of ordinary shares | (432.0) | — | — | — | — | (432.0) |
| Change in short-term borrowings, net | — | — | — | (44.4) | — | (44.4) |
| Proceeds from issuance of long-term debt | 496.5 | 2,079.2 | — | 2.2 | — | 2,577.9 |
| Payments of long-term debt | (2,012.5) | (1,150.0) | — | (2.7) | — | (3,165.2) |
| Proceeds from exercise of stock options | 17.8 | — | — | — | — | 17.8 |
| Taxes paid related to net share settlement of equity awards | (10.1) | — | — | — | — | (10.1) |
| Contingent consideration payments | — | — | — | (11.9) | — | (11.9) |
| Capital contribution from affiliates | — | — | — | 28.8 | (28.8) | — |
| Capital payments to affiliates | — | — | — | (118.6) | 118.6 | — |
| Payments on borrowings from affiliates | (1,454.2) | (3,691.6) | — | (1,536.4) | 6,682.2 | — |
| Proceeds from borrowings from affiliates | 1,383.7 | 4,350.9 | — | 445.4 | (6,180.0) | — |
| Acquisition of noncontrolling interest | — | — | — | (0.6) | — | (0.6) |
| Other items, net | — | — | — | (1.0) | — | (1.0) |
| Net cash (used in) provided by financing activities | (2,011.4) | 1,567.7 | — | (1,239.2) | 592.0 | (1,090.9) |
| Effect on cash of changes in exchange rates | — | — | — | (21.0) | — | (21.0) |
| Net (decrease) increase in cash, cash equivalents and restricted cash | — | (5.6) | — | 25.0 | — | 19.4 |
| Cash, cash equivalents and restricted cash — beginning of period | — | 23.8 | — | 346.1 | — | 369.9 |
| Cash, cash equivalents and restricted cash — end of period | \$ — | \$ 18.2 | \$ — | —\$ 371.1 | \$ — | \$ 389.3 |

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CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS

Year Ended December 31, 2017

| (In millions) | Mylan N.V. | Mylan Inc. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|--|---------------|---------------|---------------------------|-------------------------------|--------------|--------------|
| Cash flows from operating activities: | | | | | | |
| Net cash (used in) provided by operating activities | \$(326.6) | \$(381.1) | \$ | —\$ 2,772.5 | \$ | — \$ 2,064.8 |
| Cash flows from investing activities: | | | | | | |
| Capital expenditures | — | (54.8) | — | (221.1) | — | (275.9) |
| Cash paid for acquisitions, net of cash acquired | (71.6) | — | — | (95.4) | — | (167.0) |
| Proceeds from sale of assets and subsidiaries | — | — | — | 86.7 | — | 86.7 |
| Purchase of marketable securities | — | — | — | (96.5) | — | (96.5) |
| Proceeds from the sale of marketable securities | — | — | — | 96.6 | — | 96.6 |
| Investments in affiliates | — | (30.2) | — | — | 30.2 | — |
| Dividends from affiliates | 261.3 | — | — | — | (261.3) | — |
| Loans to affiliates | (322.7) | (98.0) | — | (3,493.7) | 3,914.4 | — |
| Repayments of loans from affiliates | 1,258.8 | 0.3 | — | 1,630.9 | (2,890.0) | — |
| Payments for product rights and other, net | — | (0.9) | — | (619.4) | — | (620.3) |
| Net cash provided by (used in) investing activities | 1,125.8 | (183.6) | — | (2,711.9) | 793.3 | (976.4) |
| Cash flows from financing activities: | | | | | | |
| Payments of financing fees | (9.7) | (0.4) | — | — | — | (10.1) |
| Purchase of ordinary shares | (500.2) | — | — | — | — | (500.2) |
| Change in short-term borrowings, net | — | — | — | (2.9) | — | (2.9) |
| Proceeds from issuance of long-term debt | 874.5 | — | — | 1.6 | — | 876.1 |
| Payments of long-term debt | (1,820.0) | — | — | (412.7) | — | (2,232.7) |
| Proceeds from exercise of stock options | 17.8 | — | — | — | — | 17.8 |
| Taxes paid related to net share settlement of equity awards | (7.4) | — | — | — | — | (7.4) |
| Contingent consideration payments | — | — | — | (26.1) | — | (26.1) |
| Capital contribution from affiliates | — | — | — | 30.2 | (30.2) | — |
| Capital payments to affiliates | — | — | — | (261.3) | 261.3 | — |
| Payments on borrowings from affiliates | — | (2,447.2) | — | (442.8) | 2,890.0 | — |
| Proceeds from borrowings from affiliates | 645.5 | 2,966.7 | — | 302.2 | (3,914.4) | — |
| Acquisition of noncontrolling interest | — | — | — | (7.5) | — | (7.5) |
| Other items, net | — | (16.0) | — | 15.9 | — | (0.1) |
| Net cash (used in) provided by financing activities | (799.5) | 503.1 | — | (803.4) | (793.3) | (1,893.1) |
| Effect on cash of changes in exchange rates | — | — | — | 27.6 | — | 27.6 |
| Net decrease in cash, cash equivalents and restricted cash | (0.3) | (61.6) | — | (715.2) | — | (777.1) |
| Cash, cash equivalents and restricted cash — beginning of period | 0.3 | 85.4 | — | 1,061.3 | — | 1,147.0 |
| Cash, cash equivalents and restricted cash — end of period | \$— | \$23.8 | \$ | —\$ 346.1 | \$ | — \$ 369.9 |
| Supplemental disclosures of cash flow information — | | | | | | |
| Non-cash transactions: | | | | | | |
| Contingent consideration | \$— | \$— | \$ | —\$ 4.0 | \$ | — \$ 4.0 |

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CONDENSED CONSOLIDATING STATEMENT OF CASH FLOWS

Year Ended December 31, 2016

| (In millions) | Mylan N.V. | Mylan Inc. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---------------|---------------|---------------------------|-------------------------------|--------------|--------------|
| Cash flows from operating activities: | | | | | | |
| Net cash (used in) provided by operating activities | \$(0.3) | \$(518.3) | \$ — | —\$ 2,565.8 | \$ — | \$ 2,047.2 |
| Cash flows from investing activities: | | | | | | |
| Capital expenditures | — | (94.4) | — | (296.0) | — | (390.4) |
| Cash paid for acquisitions, net of cash acquired | (5,608.8) | (931.3) | — | 58.2 | — | (6,481.9) |
| Cash paid for Meda's unconditional deferred payment | — | — | — | (308.0) | — | (308.0) |
| Settlement of acquisition-related foreign currency derivatives | (128.6) | — | — | — | — | (128.6) |
| Purchase of marketable securities | — | (4.3) | — | (25.9) | — | (30.2) |
| Proceeds from the sale of marketable securities | — | — | — | 21.5 | — | 21.5 |
| Investments in affiliates | — | (49.6) | — | — | 49.6 | — |
| Dividends from affiliates | 135.6 | — | — | — | (135.6) | — |
| Loans to affiliates | (14,073.5) | (530.2) | — | (3,185.0) | 17,788.7 | — |
| Repayments of loans from affiliates | 8,539.6 | 793.0 | — | 1,914.1 | (11,246.7) | — |
| Payments for product rights and other, net | — | 3.3 | — | (363.5) | — | (360.2) |
| Net cash used in investing activities | (11,135.7) | (813.5) | — | (2,184.6) | 6,456.0 | (7,677.8) |
| Cash flows from financing activities: | | | | | | |
| Payments of financing fees | (112.6) | — | — | — | — | (112.6) |
| Change in short-term borrowings, net | — | — | — | 40.8 | — | 40.8 |
| Contingent consideration payments | — | — | — | (35.5) | — | (35.5) |
| Proceeds from issuance of long-term debt | 11,652.6 | — | — | 99.6 | — | 11,752.2 |
| Payments of long-term debt | (400.0) | (3,400.0) | — | (2,496.3) | — | (6,296.3) |
| Proceeds from exercise of stock options | 13.8 | — | — | — | — | 13.8 |
| Taxes paid related to net share settlement of equity awards | (17.5) | — | — | — | — | (17.5) |
| Capital payments to affiliates | — | — | — | (135.6) | 135.6 | — |
| Capital contribution from affiliates | — | — | — | 49.6 | (49.6) | — |
| Proceeds from borrowings from affiliates | — | 6,961.2 | — | 10,827.6 | (17,788.8) | — |
| Payments on borrowings from affiliates | — | (3,021.9) | — | (8,224.9) | 11,246.8 | — |
| Acquisition of noncontrolling interest | — | — | — | (1.1) | — | (1.1) |
| Other items, net | — | (16.2) | — | 17.0 | — | 0.8 |
| Net cash provided by financing activities | 11,136.3 | 523.1 | — | 141.2 | (6,456.0) | 5,344.6 |
| Effect on cash of changes in exchange rates | — | — | — | (9.6) | — | (9.6) |
| Net increase (decrease) in cash, cash equivalents and restricted cash | 0.3 | (808.7) | — | 512.8 | — | (295.6) |
| Cash, cash equivalents and restricted cash — beginning of period | — | 894.1 | — | 548.5 | — | 1,442.6 |
| Cash, cash equivalents and restricted cash — end of period | \$0.3 | \$85.4 | \$ — | —\$ 1,061.3 | \$ — | \$ 1,147.0 |
| Supplemental disclosures of cash flow information | | | | | | |
| — | | | | | | |
| Non-cash transactions: | | | | | | |
| Contingent consideration | \$— | \$— | \$ — | —\$ 16.0 | \$ — | \$ 16.0 |

| | | | | | | | |
|--|-----------|-----|----|------|----|---|-----------|
| Ordinary shares issued for acquisition | \$1,281.7 | \$— | \$ | —\$— | \$ | — | \$1,281.7 |
|--|-----------|-----|----|------|----|---|-----------|

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The following tables provide a reconciliation of cash and cash equivalents, as reported on our Condensed Consolidating Balance Sheets, to cash, cash equivalents and restricted cash, as reported on our Condensed Consolidating Statements of Cash Flows (in millions):

| | December 31, 2018 | | | | Consolidated |
|--|-------------------|------------------------|----------------------------|-------------|--------------|
| | Mylan N.V. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Elimination | |
| Cash and cash equivalents | \$ 18.2 | \$ — | \$ 369.9 | \$ — | \$ 388.1 |
| Restricted cash, included in prepaid expenses and other current assets | — | — | 1.2 | — | 1.2 |
| Cash, cash equivalents and restricted cash | \$ 18.2 | \$ — | \$ 371.1 | \$ — | \$ 389.3 |
| | December 31, 2017 | | | | Consolidated |
| | Mylan N.V. | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Elimination | |
| Cash and cash equivalents | \$ 0.2 | \$ — | \$ 291.9 | \$ — | \$ 292.1 |
| Restricted cash, included in prepaid expenses and other current assets | 23.6 | — | 54.2 | — | 77.8 |
| Cash, cash equivalents and restricted cash | \$ 23.8 | \$ — | \$ 346.1 | \$ — | \$ 369.9 |

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17. Restructuring

On December 5, 2016, the Company announced a restructuring program representing initial steps of a series of actions in certain locations that are anticipated to further streamline its operations globally. Since 2015, the Company has made a number of significant acquisitions, and as part of the holistic, global integration of these acquisitions, the Company is focused on how to best optimize and maximize all of its assets across the organization and across all geographies.

Charges for restructuring and ongoing cost reduction initiatives are recorded in the period the Company commits to a restructuring or cost reduction plan, or executes specific actions contemplated by the plan and all criteria for liability recognition have been met.

During the second quarter of 2018, the Company commenced comprehensive restructuring and remediation activities, which are aimed at reducing the complexity at the Morgantown, West Virginia plant and include the discontinuation and transfer to other manufacturing sites of a number of products, a reduction of the workforce and extensive process and facility remediation. The restructuring actions other than for this plant were substantially complete as of December 31, 2018. At this time, the expenses related to the additional restructuring activities at the Morgantown, West Virginia plant cannot be reasonably estimated.

The following table summarizes the restructuring charges and the reserve activity from December 31, 2016 to December 31, 2018:

| (In millions) | Employee Related Costs | Other Exit Costs | Total |
|-------------------------------|------------------------------|------------------------|----------|
| Balance at December 31, 2016: | \$ 138.6 | \$ 1.6 | \$ 140.2 |
| Charges | 107.4 | 80.6 | 188.0 |
| Cash payment | (150.0) | (2.4) | (152.4) |
| Reclassifications | (8.3) | 8.3 | — |
| Utilization | — | (74.4) | (74.4) |
| Foreign currency translation | \$ 5.2 | \$ 0.4 | \$ 5.6 |
| Balance at December 31, 2017: | \$ 92.9 | \$ 14.1 | \$ 107.0 |
| Charges ⁽¹⁾ | 71.6 | 168.6 | 240.2 |
| Cash payment | (100.8) | (26.1) | (126.9) |
| Utilization | — | (144.5) | (144.5) |
| Foreign currency translation | (2.9) | (0.3) | (3.2) |
| Balance at December 31, 2018 | \$ 60.8 | \$ 11.8 | \$ 72.6 |

For the year ended December 31, 2018, total restructuring charges in North America, Europe, Rest of World and ⁽¹⁾corporate were approximately \$129.1 million, \$73.4 million, \$16.2 million and \$21.5 million, respectively. For the year ended December 31, 2017, total restructuring charges in North America, Europe, Rest of World and corporate were approximately \$48.0 million, \$70.1 million, \$36.5 million and \$33.4 million respectively.

At December 31, 2018 and 2017, accrued liabilities for restructuring and other cost reduction programs were primarily included in other current liabilities on the Consolidated Balance Sheets.

18. Collaboration and Licensing Agreements

We periodically enter into collaboration and licensing agreements with other pharmaceutical companies for the development, manufacture, marketing and/or sale of pharmaceutical products. Our significant collaboration agreements are primarily focused on the development, manufacturing, supply and commercialization of multiple, high-value generic biologic compounds, insulin analog products and respiratory products, among other complex products. Under these agreements, we have future potential milestone payments and co-development expenses payable to third parties as part of our licensing, development and co-development programs. Payments under these agreements generally become due and are payable upon the satisfaction or achievement of certain developmental, regulatory or commercial milestones or as development expenses are incurred on defined projects. Milestone payment

obligations are uncertain, including the prediction of timing and the occurrence of events triggering a future obligation and are not reflected as liabilities in the Consolidated Balance Sheets, except

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for milestone and royalty obligations reflected as acquisition related contingent consideration. Refer to Note 8 Financial Instruments and Risk Management for further discussion of contingent consideration. Our potential maximum development milestones not accrued for at December 31, 2018 totaled approximately \$425 million. We estimate that the amounts that may be paid in the next twelve months to be approximately \$35 million. These agreements may also include potential sales-based milestones and call for us to pay a percentage of amounts earned from the sale of the product as a royalty or a profit share. The amounts disclosed do not include sales-based milestones or royalty obligations on future sales of product as the timing and amount of future sales levels and costs to produce products subject to these obligations is not reasonably estimable. These sales-based milestones or royalty obligations may be significant depending upon the level of commercial sales for each product.

Respiratory Delivery Platform

On December 23, 2011, the Company completed the acquisition of the respiratory delivery platform. Under the agreement, the development program for the respiratory delivery platform was transferred to the Company along with exclusive licenses and assignments of the intellectual property effective from the closing date. The Company is responsible for all development costs after the closing date. The Company will also lead the commercialization efforts in certain territories, including the U.S. and Europe. Pfizer is eligible to receive milestone payments, which are contingent upon the future product development achievements including regulatory approvals, market launches, sales targets and profitability. On January 30, 2019, the Company received FDA approval of Wixela™ Inhub™ (fluticasone propionate and salmeterol inhalation powder, USP), the first generic of GlaxoSmithKline's Advair Diskus®. The commercial launch of the Wixela™ Inhub™ occurred in February 2019.

In accordance with U.S. GAAP guidance regarding business combinations, the Company accounted for this transaction as a purchase of a business and utilized the acquisition method of accounting. Under the acquisition method of accounting, the assets acquired and liabilities assumed in the transaction were recorded at the date of acquisition at the estimate of their respective fair values. The fair value of the contingent consideration liability related to the estimate of future profit sharing and milestone payments was \$336.5 million at December 31, 2018. These payments are contingent upon the occurrence of certain future events and the ultimate success of the respective projects. We estimate the amount of development milestones that may be paid in the next twelve months to be approximately \$60 million, a portion of which is accrued as contingent consideration. Given the inherent uncertainty of these events, it is unclear when we may be required to pay such amounts or pay amounts in excess of those accrued.

Momenta

On January 8, 2016, the Company entered into an agreement with Momenta Pharmaceuticals, Inc. ("Momenta") to develop, manufacture and commercialize up to six of Momenta's current biosimilar candidates, including Momenta's biosimilar candidate, ORENCIA® (abatacept) ("ORENCIA®"). Mylan paid an up-front cash payment of \$45 million to Momenta. Under the terms of the agreement, the Company and Momenta are jointly responsible for product development and equally share in the costs and profits of the products with Mylan leading the worldwide commercialization efforts.

Under the terms of the agreement, Momenta was eligible to receive additional contingent milestone payments for the development of biosimilar candidates. The Company paid \$60 million related to certain milestones in 2016. There were no milestone payments in 2017 or 2018.

On November 1, 2017, the Company and Momenta announced that M834 did not meet its primary pharmacokinetic (PK) endpoints in the Phase 1 study to compare the pharmacokinetics, safety and immunogenicity of M834 to U.S.- and European Union ("EU")-sourced ORENCIA® in normal healthy volunteers.

On January 3, 2018, the Company and Momenta announced the development strategy for M710, a proposed biosimilar to EYLEA® (aflibercept) ("EYLEA®") injection. EYLEA® is the market-leading vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy in patients with diabetic macular edema.

On October 1, 2018, Momenta announced that it had initiated discussions with Mylan to exit its participation in the development of five biosimilar programs including M834, a proposed biosimilar to ORENCIA®. The parties have

agreed to the termination of all collaboration activities, except for the continued development of M710, a proposed biosimilar to EYLEA®. The Company remains committed to invest strategically in biosimilar programs through the evaluation of regulatory data and market dynamics. The Company does not anticipate making any additional continuation payments to Momenta.

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In accordance with ASC 730, Research and Development and based upon the cost sharing provisions of the agreement, the Company accounted for the contingent milestone payments related to the Momenta collaboration as non-refundable advance payments for services to be used in future R&D activities, which were required to be capitalized until the related services have been performed. More specifically, as costs were incurred within the scope of the collaboration, the Company recorded its share of the costs as R&D expense. In addition to the upfront cash payment, during the years ended December 31, 2018, 2017, and 2016, the Company incurred R&D expense related to this collaboration of approximately \$13.4 million, \$31.9 million and \$29.2 million, respectively. To the extent the contingent milestone payments made by the Company exceeded the liability incurred, a prepaid asset was reflected on the Company's Consolidated Balance Sheets. To the extent the contingent milestone payments made by the Company were less than the expense incurred, the difference between the payment and the expense was recorded as a liability on the Company's Consolidated Balance Sheets. At December 31, 2018, there was no significant recorded prepaid asset or accrued liability on the Consolidated Balance Sheet.

Theravance

On January 30, 2015, the Company entered into a development and commercialization collaboration with Theravance Biopharma, Inc. ("Theravance Biopharma") for the development and, subject to FDA approval, commercialization of Revefenacin ("TD-4208"). Under the terms of the agreement, Mylan and Theravance Biopharma are co-developing nebulized TD-4208 for chronic obstructive pulmonary disease ("COPD") and other respiratory diseases. Theravance Biopharma is leading the U.S. registrational development program and Mylan was responsible for the reimbursement of Theravance Biopharma's development costs for that program up until the approval of the first new drug application ("NDA"). On November 9, 2018, Mylan announced that the FDA approved the NDA for YUPELRI[®] (revefenacin) inhalation solution for the maintenance treatment of patients with COPD. YUPELRI, a long-acting muscarinic antagonist (LAMA), is the first and only once-daily, nebulized bronchodilator approved for the treatment of COPD in the U.S. The commercial launch of YUPELRI occurred in the fourth quarter of 2018. Mylan is responsible for commercial manufacturing and commercialization. Theravance Biopharma is co-promoting the product in the hospital channel under a profit-sharing arrangement.

Under the terms of the agreement, Theravance Biopharma is eligible to receive potential development and sales milestone payments totaling \$220 million in the aggregate. As of December 31, 2018, Mylan has paid a total of \$30 million in milestone payments to Theravance Biopharma.

Biocon

The Company has entered into exclusive collaborations with Biocon Limited ("Biocon") on the development, manufacturing, supply and commercialization of multiple, high value biosimilar compounds and three insulin analog products for the global marketplace. Under the agreements with Biocon, Mylan has exclusive commercialization rights for the products under the collaborations in the U.S., Canada, Japan, Australia, New Zealand and in the EU and European Free Trade Association countries. Biocon has co-exclusive commercialization rights with Mylan for the products in the rest of the world.

In December 2017, the FDA approved Mylan's Ogivri[™] (trastuzumab-dkst), a biosimilar to Herceptin[®] (trastuzumab). Ogivri has been approved for all indications included in the label of the reference product, Herceptin, including for the treatment of HER2-overexpressing breast cancer and metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma). Ogivri is the first FDA-approved biosimilar to Herceptin and the first biosimilar from Mylan and Biocon's joint portfolio approved in the U.S. Mylan anticipates potentially being the first company to commercialize a biosimilar to Herceptin. In December 2018, the Company received final approval from the European Commission to market Ogivri in all 28 EU member states and the European Economic Area.

On June 4, 2018, Mylan and Biocon announced that the FDA approved Mylan's Fulphila[™] (pegfilgrastim-jmdb), a biosimilar to Neulasta[®] (pegfilgrastim). Fulphila has been approved to reduce the duration of febrile neutropenia (fever or other signs of infection with a low count of neutrophils, a type of white blood cells) in patients treated with chemotherapy in certain types of cancer. The commercial launch of Fulphila occurred in the second quarter of 2018. The Company continues to provide development funding related to this collaboration. As the timing of cash expenditures is dependent upon a number of factors, many of which are out of the Company's control, it is difficult to

forecast the amount of payments to be made over the next few years, which could be significant.

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FKB

On February 22, 2018, the Company entered into a collaboration license and distribution agreement with FKB for the distribution of Hulio™, a biosimilar to AbbVie's Humira® (adalimumab). Under the agreement, Mylan has exclusive commercialization rights for the product in the EU and the European Economic Area countries and FKB is responsible for development, manufacturing and supply of the product.

On September 20, 2018, the Company received final approval from the European Commission (the "Commission") to market Hulio for all adalimumab indications in all 28 EU member states and the European Economic Area. Under the agreement, FKB received an upfront payment of \$25.0 million, an approval milestone of \$10.0 million and is eligible for a royalty based upon net sales.

We are actively pursuing, and are currently involved in, joint projects related to the development, distribution and marketing of both generic and branded products. Many of these arrangements provide for payments by us upon the attainment of specified milestones. While these arrangements help to reduce the financial risk for unsuccessful projects, fulfillment of specified milestones or the occurrence of other obligations may result in fluctuations in cash flows and R&D expense.

19. Litigation

The Company is involved in various disputes, governmental and/or regulatory inquiries, investigations and proceedings, tax proceedings and litigation matters, both in the U.S. and abroad, that arise from time to time, some of which could result in losses, including damages, fines and/or civil penalties, and/or criminal charges against the Company. These matters are often complex and have outcomes that are difficult to predict. The Company is also party to certain proceedings and litigation matters for which it may be entitled to indemnification under the respective sale and purchase agreements relating to the acquisitions of the former Merck Generics business, Agila, Abbott Laboratories' ("Abbott") non-U.S. developed markets specialty and branded generics business, and certain other acquisitions.

While the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position, the process of resolving these matters is inherently uncertain and may develop over a long period of time, and so it is not possible to predict the ultimate resolution of any such matter. It is possible that an unfavorable resolution of any of the ongoing matters or the inability or denial of Merck KGaA, Strides Arcolab, Abbott, or another indemnitor or insurer to pay an indemnified claim, could have a material effect on the Company's business, financial condition, results of operations, cash flows and/or ordinary share price.

Some of these governmental inquiries, investigations, proceedings and litigation matters with which the Company is involved are described below, and unless otherwise disclosed, the Company is unable to predict the outcome of the matter or to provide an estimate of the range of reasonably possible material losses. The Company records accruals for loss contingencies to the extent we conclude it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company is also involved in other pending proceedings for which, in the opinion of the Company based upon facts and circumstances known at the time, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's business, financial position, results of operations, cash flows and/or ordinary share price. If and when any reasonably possible losses associated with the resolution of such other pending proceedings, in the opinion of the Company, become material, the Company will disclose such matters.

Legal costs are recorded as incurred and are classified in SG&A in the Company's Consolidated Statements of Operations.

Lorazepam and Clorazepate

On June 1, 2005, a jury verdict was rendered against Mylan, MPI, and co-defendants Cambrex Corporation and Gyma Laboratories in the U.S. District Court for the District of Columbia in the amount of approximately \$12.0 million in an antitrust case brought by four health insurers who opted out of earlier class action settlements agreed to by the Company in 2001. The Court entered final judgment on August 30, 2017 in the amount of approximately \$67.0 million (not including post-judgment interest and fees and costs). Mylan filed a notice of appeal on September 15, 2017 with the United States Court of Appeals for the District of Columbia Circuit. This matter has been resolved by

way of settlement and the case is closed. The Company paid approximately \$34.5 million during 2018 related to this matter.

The Company maintained a surety bond underwritten by a third-party insurance company in the amount of \$66.6 million which has been released.

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Pricing and Medicaid Litigation

Dey L.P. (now known as Mylan Specialty L.P. and herein as “Mylan Specialty”), a wholly owned subsidiary of the Company, was named in 1997 as a defendant in a case brought by the U.S. as well as in later filed class actions brought by consumers and third-party payors. All of the cases and claims brought against Mylan Specialty have been fully resolved and dismissed.

Under the terms of the purchase agreement with Merck KGaA, Mylan is fully indemnified for the claims in the preceding paragraph and Merck KGaA is entitled to any income tax benefit the Company realizes for any deductions of amounts paid for such pricing litigation. The Company paid approximately \$65.7 million in 2018. No further amounts are owed by the Company.

Modafinil Antitrust Litigation

Beginning in April 2006, Mylan and four other drug manufacturers were named as defendants in civil lawsuits filed in or transferred to the U.S. District Court for the Eastern District of Pennsylvania (“EDPA”) by a variety of plaintiffs purportedly representing direct and indirect purchasers of the drug modafinil and in a lawsuit filed by Apotex, Inc., a manufacturer of generic drugs. These actions alleged violations of federal antitrust and state laws in connection with the generic defendants’ settlement of patent litigation with Cephalon relating to modafinil. Mylan entered into a settlement agreement with the putative indirect purchasers for approximately \$16.0 million, which is subject to court approval. Mylan has settled with the putative direct purchaser class and the retailer opt-out plaintiffs for \$165 million, a portion of which was paid by the Company prior to 2018, and a final amount of approximately \$89.2 million was paid in April 2018. Mylan and Apotex have also settled Apotex’s claims. The Company has also received subpoenas from certain state attorneys general requesting documents related to the modafinil patent litigation.

On July 10, 2015, the Louisiana Attorney General filed in the 19th Judicial District Court in Louisiana a petition against Mylan and three other drug manufacturers asserting state law claims based on the same underlying allegations as those made in the litigation then pending in the EDPA. On December 8, 2016, Mylan’s peremptory exceptions of no cause of action with respect to the supplemental and amended petition were granted in their entirety and with prejudice. The State of Louisiana appealed this decision. The First Circuit Court of Appeal subsequently returned the case to the District Court with instructions to include certain decretal language in order to make the District Court’s decision final and appealable.

On July 28, 2016, United Healthcare filed a complaint against Mylan Inc. and four other drug manufacturers in the United States District Court for the District of Minnesota, asserting state law claims based on the same underlying allegations as those made in the litigation then pending in the EDPA. On January 6, 2017, the case was transferred to the EDPA and is still pending. MPI has since been included as an additional party. A trial date has been scheduled for July 2019.

The Company believes that it has strong defenses to these remaining cases. Although it is reasonably possible that the Company may incur additional losses from these matters, any amount cannot be reasonably estimated at this time. The Company has a total accrual of approximately \$16.0 million related to this matter at December 31, 2018, which is included in other current liabilities in the Consolidated Balance Sheets.

Pioglitazone

Beginning in December 2013, Mylan, Takeda, and several other drug manufacturers have been named as defendants in civil lawsuits consolidated in the U.S. District Court for the Southern District of New York by plaintiffs which purport to represent direct and indirect purchasers of branded or generic Actos® and Actoplus Met®. These actions allege violations of state and federal competition laws in connection with the defendants’ settlements of patent litigation in 2010 related to Actos® and Actoplus Met®. Mylan’s motion to dismiss the indirect purchasers’ complaint was granted and no appeal was filed as to Mylan. Following the appellate decision relating to other defendants, the direct purchasers filed an amended complaint against Mylan and the other manufacturers. Mylan’s motion to dismiss the amended complaint is pending.

SEC Investigation

On September 10, 2015, Mylan N.V. received a subpoena from the SEC’s Division of Enforcement seeking documents with regard to certain related party matters. Mylan subsequently received additional requests for information. The

SEC's Division of Enforcement has informed the Company that it has completed its investigation with no recommended further action.

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Trade Agreements Act (“TAA”)

On April 9, 2018, a subsidiary of Mylan N.V. received a civil investigative demand from the Commercial Litigation Branch of the U.S. Department of Justice (“DOJ”) concerning its TAA compliance for certain products. The company fully cooperated with DOJ. On September 14, 2018, the United States District Court for the Southern District of Ohio unsealed a qui tam lawsuit filed against the Mylan N.V. subsidiary concerning its TAA compliance for the same products identified in DOJ’s civil investigative demand. DOJ has declined to intervene in the lawsuit and has closed its investigation. The lawsuit has been stayed and we believe that its claims are without merit and intend to defend against them vigorously.

EpiPen® Auto-Injector and Certain Congressional Matters

Classification of EpiPen® Auto-Injector and EpiPen Jr® Auto-Injector

In November 2014, the Company received a subpoena from the DOJ related to the classification of the EpiPen® Auto-Injector for purposes of the Medicaid Drug Rebate Program (“MDRP”). On August 17, 2017, two of Mylan’s subsidiaries - Mylan Inc. and Mylan Specialty - signed an agreement for a \$465 million settlement, plus interest, with the DOJ, state government agencies and two relators (the “MDRP Settlement”). The settlement with the DOJ, two relators and all 50 states plus the District of Columbia has been completed and both the federal and state matters have been dismissed through stipulations of dismissal. In connection with the settlement, Mylan Inc. and Mylan Specialty entered into a Corporate Integrity Agreement (the “CIA”) with the Office of Inspector General of the Department of Health and Human Services. The CIA has a five-year term and requires, among other things, that an independent review organization annually review various matters relating to the MDRP. Neither the settlement agreement nor the CIA contains an admission or finding of wrongdoing. In connection with the settlement, Mylan Specialty has reclassified EpiPen® Auto-Injector as an innovator product for purposes of the MDRP effective April 1, 2017. The Company recorded an accrual for the full settlement amount during the year ended December 31, 2016 and recorded an additional accrual for interest related to the settlement amount prior to the payment made in 2017.

Department of Veterans Affairs Request for Information

On June 30, 2017, the Company responded to a request for information from the Department of Veterans Affairs (“VA”) (acting on behalf of itself and other government agencies) requesting certain historical pricing data related to the EpiPen® Auto-Injector. The Company and the VA are engaged in a continuing dialogue regarding the classification of the EpiPen® Auto-Injector as a covered drug under Section 603 of the Veterans Health Care Act of 1992, Public Law 102-585. The EpiPen® Auto-Injector has been classified as a non covered drug with the VA based upon long standing written guidance from the federal government. The Company is fully cooperating with the VA.

SEC Request for Information/Subpoenas

On October 7, 2016, Mylan received a document request from the SEC’s Division of Enforcement seeking communications with the Centers for Medicare and Medicaid Services and documents concerning Mylan products sold and related to the MDRP, and any related complaints. On November 15, 2016, Mylan received a follow-up letter, modifying the initial document request, seeking information on and public disclosures regarding the MDRP Settlement and the classification of the EpiPen® Auto-Injector under the MDRP. Mylan has received subpoenas and additional requests for information in this matter and will continue to fully cooperate with the SEC.

On April 25, 2017, Mylan received a comment letter from the staff of the SEC’s Division of Corporation Finance (“Corporation Finance”) with respect to Mylan’s Annual Report on Form 10-K for the year ended December 31, 2016, requesting information regarding Mylan’s accounting treatment of the MDRP Settlement, including with respect to the determinations that the settlement amount should be recorded as a charge against earnings in the third quarter of 2016 rather than against any earlier periods, and that the settlement amount should be classified as an expense rather than a reduction of revenue. The Company responded to the comment letter in May 2017 and we will continue to respond to any additional correspondence from Corporation Finance. We believe that our accounting treatment for the aforementioned settlement is appropriate and consistent with all applicable accounting standards.

FTC Request for Information

On November 18, 2016, Mylan received a request from the U.S. Federal Trade Commission (“FTC”) Bureau of Competition seeking documents and information relating to its preliminary investigation into potential anticompetitive

practices relating to epinephrine auto-injectors. Mylan is fully cooperating with the FTC.

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Federal Securities Litigation

Purported class action complaints were filed in October 2016 against Mylan N.V., Mylan Inc. and certain of their current and former directors and officers (collectively, for purposes of this paragraph, the “defendants”) in the United States District Court for the Southern District of New York on behalf of certain purchasers of securities of Mylan N.V. and/or Mylan Inc. on the NASDAQ. The complaints alleged that defendants made false or misleading statements and omissions of purportedly material fact, in violation of federal securities laws, in connection with disclosures relating to Mylan N.V. and Mylan Inc.’s classification of their EpiPen® Auto-Injector as a non-innovator drug for purposes of the MDRP. The complaints sought damages, as well as the plaintiffs’ fees and costs. On March 20, 2017, after the actions were consolidated, a consolidated amended complaint was filed, alleging substantially similar claims and seeking substantially similar relief, but adding allegations that defendants made false or misleading statements and omissions of purportedly material fact in connection with allegedly anticompetitive conduct with respect to EpiPen® Auto-Injector and certain generic drugs, and alleging violations of both federal securities laws (on behalf of a purported class of certain purchasers of securities of Mylan N.V. and/or Mylan Inc. on the NASDAQ) and Israeli securities laws (on behalf of a purported class of certain purchasers of securities of Mylan N.V. on the Tel Aviv Stock Exchange). On March 28, 2018, defendants’ motion to dismiss the consolidated amended complaint was granted in part (including the dismissal of claims arising under Israeli securities laws) and denied in part. On July 6, 2018, the Plaintiffs filed a second amended complaint, including certain current and former directors and officers and additional allegations in connection with purportedly anticompetitive conduct with respect to EpiPen® Auto-Injector and certain generic drugs. On August 6, 2018, defendants filed a motion to dismiss the second amended complaint, which is currently pending. We believe that the claims in this lawsuit are without merit and intend to defend against them vigorously.

Israeli Securities Litigation

On October 13, 2016, a purported shareholder of Mylan N.V. filed a lawsuit, together with a motion to certify the lawsuit as a class action on behalf of certain Mylan N.V. shareholders on the Tel Aviv Stock Exchange, against Mylan N.V. and four of its directors and officers (collectively, for purposes of this paragraph, the “defendants”) in the Tel Aviv District Court (Economic Division) (the “Friedman Action”). The plaintiff alleges that the defendants made false or misleading statements and omissions of purportedly material fact in Mylan N.V.’s reports to the Tel Aviv Stock Exchange regarding Mylan N.V.’s classification of its EpiPen® Auto-Injector for purposes of the MDRP, in violation of both U.S. and Israeli securities laws, the Israeli Companies Law and the Israeli Torts Ordinance. The plaintiff seeks damages, among other remedies. On April 30, 2017, another purported shareholder of Mylan N.V. filed a separate lawsuit, together with a motion to certify the lawsuit as a class action on behalf of certain Mylan N.V. shareholders on the Tel Aviv Stock Exchange, in the Tel Aviv District Court (Economic Division), alleging substantially similar claims and seeking substantially similar relief against the defendants and other directors and officers of Mylan N.V., but alleging also that this group of defendants made false or misleading statements and omissions of purportedly material fact in connection with allegedly anticompetitive conduct with respect to EpiPen® Auto-Injector and certain generic drugs, and alleging violations of both U.S. federal securities laws and Israeli law (the “IEC Fund Action”). On April 10, 2018, the Tel Aviv District Court granted the motion filed by plaintiffs in both the Friedman Action and the IEC Fund Action, voluntarily dismissing the Friedman Action and staying the IEC Fund Action until a judgment is issued in the securities litigation pending in the U.S. We believe that the claims in these lawsuits are without merit and intend to defend against them vigorously.

EpiPen® Auto-Injector Civil Litigation

Mylan Specialty and other Mylan-affiliated entities have been named as defendants in putative class actions relating to the pricing and/or marketing of the EpiPen® Auto-Injector. The plaintiffs in these cases assert violations of various federal and state antitrust and consumer protection laws, the Racketeer Influenced and Corrupt Organizations Act, as well as common law claims. Plaintiffs’ claims include purported challenges to the prices charged for the EpiPen® Auto-Injector and/or the marketing of the product in packages containing two auto-injectors, as well as allegedly anti-competitive conduct. A Mylan officer and other non-Mylan affiliated companies were also named as defendants in some of the class actions. These lawsuits were filed in the various federal and state courts and have either been

dismissed or transferred into a multidistrict litigation (“MDL”) in the U.S. District Court for the District of Kansas and have been consolidated. Mylan filed a motion to dismiss the consolidated amended complaint, which was granted in part and denied in part. On December 7, 2018, the Plaintiffs filed a motion for class certification. This motion remains pending. A trial date has been scheduled for July 2020. We believe that the remaining claims in these lawsuits are without merit and intend to defend against them vigorously.

On April 24, 2017, Sanofi-Aventis U.S., LLC (“Sanofi”) filed a lawsuit against Mylan Inc. and Mylan Specialty in the U.S. District Court for the District of New Jersey. This lawsuit has been transferred into the aforementioned MDL. In this lawsuit, Sanofi alleges exclusive dealings and anti-competitive marketing practices in violation of the antitrust laws in connection with the sale and marketing of the EpiPen® Auto-Injector. On November 1, 2018, Sanofi filed a Motion for a

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Suggestion of Remand of the case to the U.S. District Court for the District of New Jersey. On January 23, 2019, the Court denied Sanofi's motion without prejudice. We believe that Sanofi's claims in this lawsuit are without merit and intend to defend against them vigorously.

EpiPen® Auto-Injector State AG Investigations

The Company and certain of its affiliated entities received subpoenas and informal requests from various state attorneys general seeking information and documents relating to the pricing and/or marketing of the EpiPen® Auto-Injector. The Company has cooperated and is fully cooperating with the various state attorneys general.

U.S. Congress/State Requests for Information and Documents

Mylan received several requests for information and documents from various Committees of the U.S. Congress and federal and state lawmakers concerning the marketing, distribution and sales of Mylan products. Mylan cooperated with federal and state lawmakers as appropriate in response to their requests.

The Company has a total accrual of approximately \$10.0 million related to this matter at December 31, 2018, which is included in other current liabilities in the Consolidated Balance Sheets. During the year ended December 31, 2018, the Company made payments of approximately \$472.7 million related to this matter. The Company believes that it has strong defenses to current and future potential civil litigation, as well as governmental investigations and enforcement proceedings, discussed in this "EpiPen® Auto-Injector and Certain Congressional Matters" section of this Note 19 Litigation. Although it is reasonably possible that the Company may incur additional losses from these matters, any amount cannot be reasonably estimated at this time. In addition, the Company expects to incur additional legal and other professional service expenses associated with such matters in future periods and will recognize these expenses as services are received. The Company believes that the ultimate amount paid for these services and claims could have a material effect on the Company's business, financial condition, results of operations, cash flows and/or ordinary share price in future periods.

Opioids

On July 27, 2017, Mylan N.V. received a subpoena from the DOJ seeking information relating to opioids manufactured, marketed or sold by Mylan during the period from January 1, 2013 to December 31, 2016. On August 29, 2017, Mylan N.V. received a civil investigative demand from the Attorney General of the State of Missouri seeking information relating to opioids manufactured, marketed or sold by Mylan during the period from January 1, 2010 to the present and related subject matter. Mylan is fully cooperating with these subpoena requests.

Mylan has been named in the U.S. and Canada, along with numerous other manufacturers, distributors, pharmacies, pharmacy benefit managers, and/or individual healthcare professionals, in civil lawsuits, including certain cases in the MDL pending in the United States District Court for the Northern District of Ohio, brought by plaintiffs, including local governmental entities, generally asserting statutory and/or common law claims arising from the manufacture, distribution, marketing, promotion, and sale of purported prescription opioids. The lawsuits seek damages, including punitive and/or exemplary damages, injunctive relief, attorneys' fees and costs, and other relief. Mylan believes that the claims in these lawsuits are without merit and intends to defend against them vigorously.

Drug Pricing Matters

Department of Justice

On December 3, 2015, a subsidiary of Mylan N.V. received a subpoena from the Antitrust Division of the DOJ seeking information relating to the marketing, pricing, and sale of our generic Doxycycline products and any communications with competitors about such products.

On September 8, 2016, a subsidiary of Mylan N.V., as well as certain employees and a member of senior management, received subpoenas from the DOJ seeking additional information relating to the marketing, pricing and sale of our generic Cidofovir, Glipizide-metformin, Propranolol and Verapamil products and any communications with competitors about such products. Related search warrants also were executed.

On May 10, 2018, a subsidiary of Mylan N.V. received a civil investigative demand from the Civil Division of the DOJ seeking information relating to the pricing and sale of its generic drug products.

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The Company is fully cooperating with the DOJ.

Civil Litigation

Beginning in 2016, the Company, along with other manufacturers, has been named as a defendant in lawsuits generally alleging anticompetitive conduct with respect to generic drugs. The lawsuits have been filed by putative classes of direct purchasers, indirect purchasers, and indirect resellers, as well as individual direct and indirect purchasers. They allege harm under federal and state antitrust laws, state consumer protection laws and unjust enrichment claims. Some of the lawsuits also name Mylan's President as a defendant and include allegations against him with respect to doxycycline hyclate delayed release. The lawsuits have been consolidated in an MDL proceeding in the EDPA. The Court has sequenced these lawsuits into separate groups for purposes of briefing motions to dismiss. Defendants filed motions to dismiss complaints in the first group. On October 16, 2018, the Court denied the motions with respect to the federal law claims. On February 15, 2019, the Court granted in part and denied in part the motions with respect to the state law claims. The Company believes that the claims in these lawsuits are without merit and intends to defend against them vigorously.

Attorneys General Litigation

On December 21, 2015, the Company received a subpoena and interrogatories from the Connecticut Office of the Attorney General seeking information relating to the marketing, pricing and sale of certain of the Company's generic products (including generic doxycycline) and communications with competitors about such products. On December 14, 2016, attorneys general of twenty states filed a complaint in the United States District Court for the District of Connecticut against several generic pharmaceutical drug manufacturers, including Mylan, alleging anticompetitive conduct with respect to, among other things, doxycycline hyclate delayed release. The complaint was subsequently amended to add certain attorneys general alleging violations of federal and state antitrust laws, as well as violations of various states' consumer protection laws. This lawsuit has been transferred to the aforementioned MDL proceeding in the EDPA. On October 31, 2017, attorneys general of forty-five states, the District of Columbia and the Commonwealth of Puerto Rico filed a motion for leave to file a consolidated amended complaint ("proposed amended complaint") against various drug manufacturers, including Mylan. The proposed amended complaint was permitted and was filed on June 18, 2018 and included two additional states. Mylan is alleged to have engaged in anticompetitive conduct with respect to doxycycline hyclate delayed release, doxycycline monohydrate, glipizide-metformin, and verapamil. The amended complaint also includes claims asserted by attorneys general of thirty-seven states and the Commonwealth of Puerto Rico against certain individuals, including Mylan's President, with respect to doxycycline hyclate delayed release. The allegations in the amended complaint are similar to those in the previously filed complaints. We believe that the claims in this lawsuit are without merit and intend to defend against them vigorously.

Valsartan

Mylan N.V., and three of its subsidiaries (Mylan Inc., Mylan Laboratories Ltd. and Mylan Pharmaceuticals Inc.), along with numerous other manufacturers, retailers and others, have been named as defendants in lawsuits in the United States and Israel stemming from recalls of valsartan-containing medications. The litigation, which will take place in an MDL in the District of New Jersey, includes class action allegations seeking the refund of the purchase price and other economic damages allegedly sustained by consumers who purchased valsartan-containing products as well as claims for personal injuries allegedly caused by ingestion of the medication. Moreover, Mylan has received requests to indemnify purchasers of Mylan's active pharmaceutical ingredient and/or finished dose forms of the product. We believe that the claims in these lawsuits are without merit and intend to defend against them vigorously.

European Commission Proceedings

Perindopril

On July 9, 2014, the Commission issued a decision finding that Mylan Laboratories Limited and Mylan, as well as several other companies, had violated EU competition rules relating to the product Perindopril and fined Mylan Laboratories Limited approximately €17.2 million, including approximately €8.0 million jointly and severally with Mylan Inc. The Company paid approximately \$21.7 million related to this matter during the fourth quarter of 2014. In September 2014, the Company filed an appeal of the Commission's decision to the General Court of the EU. A hearing on the appeal before the General Court of the EU was held in June 2017 and the Commission's decision was affirmed.

Mylan is preparing to appeal this decision to the European Court of Justice (“CJEU”).

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Citalopram

On June 19, 2013, the Commission issued a decision finding that Generics [U.K.] Limited, (“GUK”) as well as several other companies, had violated EU competition rules relating to the product Citalopram and fined GUK approximately €7.8 million, jointly and severally with Merck KGaA. GUK appealed the Commission’s decision to the General Court of the EU. The case is currently on appeal to the CJEU. The U.K. applied and was granted permission to intervene in this proceeding. The Company has accrued approximately €7.4 million as of December 31, 2018 and 2017, respectively related to this matter. GUK has received notices from European national health services and health insurers stating an intention to commence follow-on litigation and asserting damages. GUK has also sought indemnification from Merck KGaA with respect to the €7.8 million portion of the fine for which Merck KGaA and GUK were held jointly and severally liable. Merck KGaA has counterclaimed against GUK seeking the same indemnification. In June 2018, the Frankfurt Regional Court issued a judgment dismissing GUK claims against Merck KGaA and ordered GUK to indemnify Merck KGaA with respect to the amount for which the parties were held jointly and severally liable. GUK has appealed this decision. A hearing took place on January 24, 2019. It is reasonably possible that we will incur additional losses above the amount accrued but we cannot estimate a range of such reasonably possible losses at this time. There are no assurances, however, that settlements reached and/or adverse judgments received, if any, will not exceed amounts accrued.

U.K. Competition and Markets Authority

Paroxetine

On August 12, 2011, GUK received notice that the Office of Fair Trading (subsequently changed to the Competition and Markets Authority (the “CMA”)) opened an investigation to explore the possible infringement of the Competition Act 1998 and Articles 101 and 102 of the Treaty on the Functioning of the EU, with respect to alleged agreements related to Paroxetine. The CMA issued a decision on February 12, 2016, finding that, GUK, Merck KGaA and other companies were liable for infringing EU and U.K. competition rules. With respect to Merck KGaA and GUK, the CMA issued a penalty of approximately £5.8 million, for which Merck KGaA is liable for the entire amount; and of that amount GUK is jointly and severally liable for approximately £2.7 million, which has been accrued for as of December 31, 2018. The matter is currently on appeal to the Competition Appeals Tribunal, which on March 8, 2018, referred certain questions of law to the CJEU. The CJEU sought written observations from GUK, which were filed in September 2018.

Nefopam

On October 10, 2017, Mylan N.V. and Meda Pharmaceuticals Limited received notice that the CMA was opening an investigation to explore the possible infringement of the Competition Act 1998 and Article 101 of the Treaty on the Functioning of the EU, with respect to alleged agreements related to Nefopam, a product from Meda’s portfolio. On October 16, 2017, the CMA issued a notice under Section 26 of the Competition Act 1998 to Mylan N.V. and Meda Pharmaceuticals Limited to provide specified information and produce specified documents. The CMA has closed its investigation with no action.

Italy Investigation

On April 18, 2018, certain employees of Mylan S.p.A. were served with search warrants issued by the Public Prosecutor’s Office in Milan, Italy seeking information concerning interactions with an Italian hospital and sales of certain reimbursable Mylan S.p.A. drugs. The Company is assisting its employees in their cooperation with the investigation.

Table of Contents**Product Liability**

The Company is involved in a number of product liability lawsuits and claims related to alleged personal injuries arising out of certain products manufactured and/or distributed by the Company. The Company believes that it has meritorious defenses to these lawsuits and claims and is vigorously defending itself with respect to those matters. From time to time, the Company has agreed to settle or otherwise resolve certain lawsuits and claims on terms and conditions that are in the best interests of the Company. The Company has accrued approximately \$10.9 million and \$8.4 million at December 31, 2018 and December 31, 2017, respectively. It is reasonably possible that we will incur additional losses and fees above the amount accrued but we cannot estimate a range of such reasonably possible losses or legal fees related to these claims at this time. There are no assurances, however, that settlements reached and/or adverse judgments received, if any, will not exceed amounts accrued.

Intellectual Property

MPI filed with the FDA a Paragraph IV certification stating that approval of MPI's Abbreviated New Drug Application ("ANDA") for glatiramer acetate injection, 20 mg/mL will not infringe any valid claim of patents owned or controlled by Teva Pharmaceuticals USA, Inc., Yeda Research and Development Co., or their affiliates (for purposes of these paragraphs, "Plaintiffs"), listed in the FDA's Orange Book. There are currently no unexpired patents for the product listed in the FDA's Orange Book. On October 3, 2017, MPI received final FDA approval and launched its 20 mg/mL glatiramer acetate product in the U.S.

MPI filed with the FDA a Paragraph IV certification stating that approval of MPI's ANDA for glatiramer acetate injection, 40 mg/mL will not infringe any valid claim of patents owned or controlled by the Plaintiffs listed in the FDA's Orange Book. On October 6, 2014, Plaintiffs filed suit against MPI and Mylan Inc. in the District Court for the District of Delaware alleging infringement of the Orange Book patents and seeking monetary damages, injunctive relief, attorneys' fees, costs and other relief. On January 30, 2017, the Delaware District Court found, after trial, the asserted claims of the Orange Book patents-in-suit invalid as obvious.

In February and March 2015, MPI and Mylan Inc. filed petitions with the Patent Trial and Appeal Board requesting inter partes review of the claims of three asserted patents. On August 24, 2016 and September 1, 2016, respectively, the Patent Trial and Appeal Board issued final written decisions finding all claims of three asserted patents unpatentable as obvious. After Plaintiffs' requests for reconsideration of those decisions, the Patent Trial and Appeal Board issued revised final written decisions addressing issues raised in the requests for reconsideration and again finding all claims of three asserted patents unpatentable as obvious.

Plaintiffs appealed both the District Court decision and the Patent and Trial and Appeal Board decision to the Federal Circuit. On October 12, 2018, the Federal Circuit affirmed both decisions finding the asserted claims of the Orange Book-listed patents invalid. No further appeals were filed, and all deadlines have passed.

On October 19, 2017, Teva Pharmaceutical Industries Ltd. ("Teva") commenced an action with the Irish High Court against Mylan Teoranta alleging that Mylan's glatiramer acetate 40mg/mL product, which is manufactured in Ireland, approved by the FDA and is currently being sold in the U.S., infringes two European patents, EP (IE) 2 949 335 and EP (IE) 3 050 556. Teva subsequently dropped its infringement allegation related to the EP (IE) 3 050 556 patent. Teva is seeking damages and/or an account of profits from Mylan for the alleged infringement. Teva has also requested the Irish High Court to enjoin Mylan Teoranta from making, offering, putting on the market and/or using its glatiramer acetate 40mg/mL product in Ireland pending final determination of the action. On June 5, 2018, the Irish High Court refused Teva's request for an injunction pending final determination. Teva has appealed the decision and an injunction appeal hearing is scheduled for June 26, 2019. A main trial on the infringement and validity of the 335 patent is scheduled to begin on July 9, 2019.

On September 22, 2017, Amgen Inc. and Amgen Manufacturing Limited ("Amgen") sued Mylan Inc., Mylan N.V., Mylan GMBH, and MPI in the Western District of Pennsylvania asserting that Mylan's Fulphila® infringes U.S. patent numbers 8,273,707 and 9,643,997. On June 4, 2018, the FDA approved Mylan's Fulphila® (pegfilgrastim-jmdb), a biosimilar to Neulasta® (pegfilgrastim), co-developed with Biocon. In July 2018, Mylan began selling Fulphila®. Amgen is seeking monetary damages, injunctive relief, attorneys' fees, costs and other relief. No trial date is currently scheduled.

On July 31, 2015, BTG International Ltd., Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC (“Janssen”) sued Mylan Inc. and Mylan Pharmaceuticals, Inc., along with numerous other ANDA applicants, in the District of New Jersey asserting that Mylan’s and the other ANDA applicants’ abiraterone acetate ANDA products infringe U.S. Patent number 8,822,438 (“438”). On June 30, 2016, Mylan filed an Inter Partes Review (“IPR”)

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petition challenging the validity of the '438 patents' claims. On January 17, 2018, the U.S. Patent and Trademark Appeal Board ("PTAB") issued Final Written Decisions in the IPR finding all claims of the '438 patent unpatentable as obvious. On October 26, 2018, the district court issued an opinion similarly finding the '438 patents' claims invalid as obvious. On October 31, 2018, the FDA approved Mylan's abiraterone acetate ANDA. Mylan, along with certain other ANDA applicants, began selling their abiraterone acetate ANDA products in November.

Janssen has appealed both the district court and IPR decisions to the Federal Circuit. Both matters have been consolidated and a hearing is set on the appeals for March 14, 2019. Janssen is seeking monetary damages, injunctive relief, attorneys' fees, costs and other relief, including pre- and post-judgment interest. Janssen is further asserting that the district court erred in not enforcing estoppel provisions against the prevailing ANDA filers in the IPR proceedings.

The Company has used its business judgment in connection with the decision to launch the 40mg/mL glatiramer acetate, Fulphila® and abiraterone acetate products and has also used its business judgment in certain other situations to decide to market and sell products, in each case based on its belief that the applicable patents are invalid and/or that its products do not infringe, notwithstanding the fact that allegations of patent infringement(s) or other potential third party rights have not been finally resolved by the courts. The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, a reasonable royalty on sales or damages measured by the profits lost by the patent owner. If there is a finding of willful infringement, damages may be increased up to three times. Moreover, because of the discount pricing typically involved with bioequivalent products, patented branded products generally realize a substantially higher profit margin than generic and biosimilar products. Mylan intends to defend against any such patent infringement claims vigorously. However, an adverse decision could have an adverse effect that is material to our business, financial condition, results of operations, cash flows and/or ordinary share price.

Other Litigation

The Company is involved in various other legal proceedings that are considered normal to its business. The Company has approximately \$5.5 million accrued related to these various other legal proceedings at December 31, 2018.

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Mylan N.V.

Supplementary Financial Information

Quarterly Financial Data

(Unaudited, in millions, except per share data)

Year Ended December 31, 2018

| | Three-Month Period Ended | | | |
|-------------------------------------|--------------------------|------------------|-----------------------|----------------------|
| | March 31, 2018 | June 30, 2018 | September 30, 2018 | December 31, 2018 |
| Total revenues | \$2,684.5 | \$2,808.3 | \$ 2,862.4 | \$ 3,078.7 |
| Gross profit | 984.3 | 962.5 | 1,039.2 | 1,015.6 |
| Net earnings | 87.1 | 37.5 | 176.7 | 51.2 |
| Earnings per share ⁽¹⁾ : | | | | |
| Basic | \$0.17 | \$0.07 | \$ 0.34 | \$ 0.10 |
| Diluted | \$0.17 | \$0.07 | \$ 0.34 | \$ 0.10 |
| Share prices ⁽²⁾ : | | | | |
| High | \$47.64 | \$41.86 | \$ 39.48 | \$ 37.15 |
| Low | \$38.87 | \$35.37 | \$ 35.53 | \$ 26.21 |

Year Ended December 31, 2017

| | Three-Month Period Ended | | | |
|-------------------------------------|--------------------------|------------------|-----------------------|----------------------|
| | March 31, 2017 | June 30, 2017 | September 30, 2017 | December 31, 2017 |
| Total revenues | \$2,719.5 | \$2,962.2 | \$ 2,987.1 | \$ 3,238.9 |
| Gross profit | 1,085.0 | 1,225.4 | 1,178.1 | 1,294.6 |
| Net earnings | 66.4 | 297.0 | 88.3 | 244.3 |
| Earnings per share ⁽¹⁾ : | | | | |
| Basic | \$0.12 | \$0.56 | \$ 0.17 | \$ 0.46 |
| Diluted | \$0.12 | \$0.55 | \$ 0.16 | \$ 0.46 |
| Share prices ⁽²⁾ : | | | | |
| High | \$45.28 | \$40.09 | \$ 39.49 | \$ 42.31 |
| Low | \$35.81 | \$36.72 | \$ 29.63 | \$ 32.39 |

⁽¹⁾ The sum of earnings per share for the quarters may not equal earnings per share for the total year due to changes in the average number of ordinary shares outstanding.

⁽²⁾ Closing prices are as reported on NASDAQ.

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ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

None.

ITEM 9A. Controls and Procedures

An evaluation was performed under the supervision and with the participation of the Company's management, including the Principal Executive Officer and the Principal Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of December 31, 2018. Based upon that evaluation, the Principal Executive Officer and the Principal Financial Officer concluded that the Company's disclosure controls and procedures were effective.

Management has not identified any changes in the Company's internal control over financial reporting that occurred during the fourth quarter of 2018 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting is on page 71, which is incorporated herein by reference. The effectiveness of the Company's internal control over financial reporting as of December 31, 2018 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report on page 73, which is incorporated herein by reference.

ITEM 9B. Other Information

Credit Agreement Amendments

On February 22, 2019, the Company, as a guarantor, and Mylan Inc., as borrower, entered into the Revolving Loan Amendment to the 2018 Revolving Facility. In addition, on February 22, 2019, the Company entered into the Term Loan Amendment to the 2016 Term Facility. The Revolving Loan Amendment and the Term Loan Amendment extended the leverage ratio covenant of 4.25 to 1.00 through the December 31, 2019 reporting period, with a leverage ratio of 3.75 to 1.00 thereafter. The Company is in compliance at December 31, 2018 and expects to remain in compliance for the next twelve months.

The foregoing description does not purport to be complete and is qualified in its entirety by reference to the Revolving Loan Amendment and the Term Loan Amendment, which are attached hereto as Exhibit 10.34(b) and Exhibit 10.35(c), respectively, and which are incorporated herein by reference.

Agreements with Named Executive Officers

On February 25, 2019, Mylan extended the employment agreements of Heather Bresch, Chief Executive Officer, Rajiv Malik, President, Ken Parks, Chief Financial Officer, and Anthony Mauro, Chief Commercial Officer. The term of the agreements extends through April 1, 2024 for Ms. Bresch and through April 1, 2022 for each of Messrs. Malik, Parks and Mauro, and each will renew for successive one-year terms thereafter. Pursuant to the extended agreements, base salaries are \$1,500,000 for Ms. Bresch, \$1,150,000 for Mr. Malik, and \$800,000 for Messrs. Parks and Mauro. Ms. Bresch is eligible for a target annual bonus of 150% of base salary and Messrs. Malik, Parks and Mauro are eligible for target annual bonuses of 125%, 115% and 115% of base salary, respectively.

As previously disclosed on February 11, 2019, Daniel M. Gallagher, Chief Legal Officer, informed Mylan that he intends to return to private practice in the Washington, D.C. area at the conclusion of the current term of his employment agreement in April 2019. On February 25, 2019, Mylan and Mr. Gallagher entered into a consulting agreement setting forth the terms of his separation and continuing consulting role for up to 12 months following the separation date. Mr. Gallagher will receive (i) a cash payment of \$800,000 payable pursuant to his employment agreement, (ii) payments of \$50,000 per month in consideration of the consulting services to be provided, (iii) eligibility for continued vesting of 32,354 time-based restricted stock units and unvested retirement plan contributions through the term of the consulting agreement and (iv) continued medical and welfare benefits through the 12 month anniversary of his separation pursuant to his employment agreement.

This description of the employment agreements and consulting agreement is qualified by reference to the provisions of the applicable agreements, copies of which are filed as exhibits to this Annual Report on Form 10-K.

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PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

Certain information required by this Item will be provided in an amendment to this Annual Report on Form 10-K in accordance with General Instruction G(3) to Form 10-K.

Code of Ethics

The Mylan board of directors has adopted a Code of Ethics for the Company's Chief Executive Officer, Chief Financial Officer and Controller. The Mylan board of directors also has adopted a Code of Business Conduct and Ethics applicable to all directors, officers, and employees. The Code of Ethics for our Chief Executive Officer, Chief Financial Officer and Controller and the Code of Business Conduct and Ethics are posted on Mylan's website at <http://www.mylan.com/company/corporate-governance>, and Mylan intends to post any amendments to and waivers from each of the Code of Ethics for the Company's Chief Executive Officer, Chief Financial Officer and Controller and the Code of Business Conduct and Ethics that are required to be disclosed on that website.

ITEM 11. Executive Compensation

The information required by this Item will be provided in an amendment to this Annual Report on Form 10-K in accordance with General Instruction G(3) to Form 10-K.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The additional information required by this Item will be provided in an amendment to this Form 10-K in accordance with General Instruction G(3) to Form 10-K.

Equity Compensation Plan Information

The following table shows information about the securities authorized for issuance under Mylan's equity compensation plans as of December 31, 2018:

| Plan Category | Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a) | Weighted-Average Price of Outstanding Options, Warrants and Rights (b) | Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c) |
|--|---|--|---|
| Equity compensation plans approved by security holders | 13,208,359 | \$ 38.61 | 7,953,085 |
| Equity compensation plans not approved by security holders | — | — | — |
| Total | 13,208,359 | \$ 38.61 | 7,953,085 |

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item will be provided in an amendment to this Annual Report on Form 10-K in accordance with General Instruction G(3) to Form 10-K.

ITEM 14. Principal Accounting Fees and Services

The information required by this Item will be provided in an amendment to this Annual Report on Form 10-K in accordance with General Instruction G(3) to Form 10-K.

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PART IV

ITEM 15. Exhibits, Consolidated Financial Statement Schedules

1. Consolidated Financial Statements

The Consolidated Financial Statements listed in the Index to Consolidated Financial Statements are filed as part of this Form.

2. Consolidated Financial Statement Schedules

MYLAN N.V. AND SUBSIDIARIES

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

(In millions)

| Description | Beginning Balance | Additions Charged to Costs and Expenses | Additions Charged to Other Accounts ⁽¹⁾ | Deductions | Ending Balance |
|--|-------------------|---|--|------------|----------------|
| Allowance for doubtful accounts: | | | | | |
| Year ended December 31, 2018 | \$ 75.3 | 32.3 | 0.2 | (9.6) | \$ 98.2 |
| Year ended December 31, 2017 | \$ 59.0 | 16.8 | 6.0 | (6.5) | \$ 75.3 |
| Year ended December 31, 2016 | \$ 33.6 | 15.6 | 13.0 | (3.2) | \$ 59.0 |
| Valuation allowance for deferred tax assets: | | | | | |
| Year ended December 31, 2018 | \$ 662.8 | 203.8 | — | (60.6) | \$ 806.0 |
| Year ended December 31, 2017 | \$ 460.7 | 194.1 | 18.9 | (10.9) | \$ 662.8 |
| Year ended December 31, 2016 | \$ 355.7 | 108.8 | 3.4 | (7.2) | \$ 460.7 |

(1) In 2016, this amount includes opening balances of businesses acquired in the period.

3. Exhibits

2.1 Amended and Restated Business Transfer Agreement and Plan of Merger, dated November 4, 2014, between and among Abbott Laboratories, Mylan Inc., New Moon B.V. and Moon of PA Inc., filed as Annex A to the Registration Statement on Form S-4 filed with the SEC on November 5, 2014, as amended on December 9 and December 23, 2014, and incorporated herein by reference.[^]

2.2(a) Irrevocable Undertaking, dated February 10, 2016, between Mylan N.V. and Stena Sessan Rederi AB, filed as Exhibit 2.1 to the Report on Form 8-K filed with the SEC on February 17, 2016, and incorporated herein by reference.

2.2(b) Irrevocable Undertaking, dated February 10, 2016, between Mylan N.V. and Fidim S.r.l., filed as Exhibit 2.2 to the Report on Form 8-K filed with the SEC on February 17, 2016, and incorporated herein by reference.

2.2(c) Shareholder Agreement, dated February 10, 2016, between Mylan N.V. and Stena Sessan Rederi AB, filed as Exhibit 2.3 to the Report on Form 8-K filed with the SEC on February 17, 2016, and incorporated herein by reference.[^]

2.2(d) Shareholder Agreement, dated February 10, 2016, between Mylan N.V. and Fidim S.r.l., filed as Exhibit 2.4 to the Report on Form 8-K filed with the SEC on February 17, 2016, and incorporated herein by reference.[^]

3.1 Amended and Restated Articles of Association of Mylan N.V., filed as Exhibit 3.1 to the Report on Form 8-K filed with the SEC on February 27, 2015, and incorporated herein by reference.

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- 4.1(a) Indenture, dated December 21, 2012, between and among Mylan Inc., the guarantors named therein, and The Bank of New York Mellon, as trustee, filed by Mylan Inc. as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on December 24, 2012, and incorporated herein by reference.
- 4.1(b) First Supplemental Indenture, dated February 27, 2015, between and among Mylan Inc., as Issuer, Mylan N.V., as Guarantor, and The Bank of New York Mellon, as Trustee, to the Indenture, dated December 21, 2012, filed as Exhibit 4.4 to the Report on Form 8-K filed with the SEC on February 27, 2015, and incorporated herein by reference.
- 4.1(c) Second Supplemental Indenture, dated March 12, 2015, between and among Mylan Inc., as Issuer, Mylan N.V., as Parent, and The Bank of New York Mellon, as Trustee, to the Indenture, dated December 21, 2012, filed as Exhibit 4.3(b) to Form 10-Q for the quarter ended March 31, 2015, and incorporated herein by reference.
- 4.2(a) Indenture, dated June 25, 2013, among Mylan Inc., the guarantors thereto and The Bank of New York Mellon, as trustee, filed by Mylan Inc. as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on June 27, 2013, and incorporated herein by reference.
- 4.2(b) First Supplemental Indenture, dated February 27, 2015, between and among Mylan Inc., as Issuer, Mylan N.V., as Guarantor, and The Bank of New York Mellon, as Trustee, to the Indenture, dated June 25, 2013, filed as Exhibit 4.5 to the Report on Form 8-K filed with the SEC on February 27, 2015, and incorporated herein by reference.
- 4.2(c) Second Supplemental Indenture, dated March 12, 2015, between and among Mylan Inc., as Issuer, Mylan N.V., as Parent, and The Bank of New York Mellon, as Trustee, to the Indenture, dated June 25, 2013, filed as Exhibit 4.4(b) to Form 10-Q for the quarter ended March 31, 2015, and incorporated herein by reference.
- 4.3(a) Indenture, dated November 29, 2013, by and between Mylan Inc. and The Bank of New York Mellon, as trustee, filed by Mylan Inc. as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on November 29, 2013, and incorporated herein by reference.
- 4.3(b) First Supplemental Indenture, dated November 29, 2013, by and between Mylan Inc. and The Bank of New York Mellon, as trustee, filed by Mylan Inc. as Exhibit 4.2 to the Report on Form 8-K filed with the SEC on November 29, 2013, and incorporated herein by reference.
- 4.3(c) Second Supplemental Indenture, dated February 27, 2015, between and among Mylan Inc., as Issuer, Mylan N.V., as Guarantor, and The Bank of New York Mellon, as Trustee, to the Indenture, dated November 29, 2013, filed as Exhibit 4.6 to the Report on Form 8-K filed with the SEC on February 27, 2015, and incorporated herein by reference.
- 4.3(d) Third Supplemental Indenture, dated March 12, 2015, between and among Mylan Inc., as Issuer, Mylan N.V., as Parent, and The Bank of New York Mellon, as Trustee, to the Indenture, dated November 29, 2013, filed as Exhibit 4.5(b) to Form 10-Q for the quarter ended March 31, 2015, and incorporated herein by reference.
- 4.4 Indenture, dated as of December 9, 2015, among Mylan N.V., Mylan Inc., as guarantor, and The Bank of New York Mellon, as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on December 15, 2015, and incorporated herein by reference.
- 4.5 Indenture, dated as of June 9, 2016, among Mylan N.V., as issuer, Mylan Inc., as guarantor, and The Bank of New York Mellon, as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on June 15, 2016, and incorporated herein by reference.
- 4.6 Indenture, dated November 22, 2016, among Mylan N.V., as issuer, Mylan, Inc., as guarantor and Citibank, N.A., London Branch, as trustee, filed as Exhibit 4.9 to Form 10-K for the fiscal year ended December 31, 2016, and incorporated herein by reference.
- 4.7 Indenture, dated as of May 24, 2017, among Mylan N.V., as issuer, Mylan Inc., as guarantor, and Citibank, N.A., London Branch, as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on May 31, 2017, and incorporated herein by reference.

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4.8 Indenture, dated as of April 9, 2018, among Mylan Inc., Mylan N.V., as guarantor, and the Bank of New York Mellon, as trustee, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on April 9, 2018, and incorporated herein by reference.

4.9 Indenture, dated as of May 23, 2018, among Mylan Inc., Mylan N.V., as guarantor, and Citibank, N.A., London Branch, as trustee, paying agent, transfer agent and registrar, filed as Exhibit 4.1 to the Report on Form 8-K filed with the SEC on May 23, 2018, and incorporated herein by reference.

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- 10.1(a) Amended and Restated 2003 Long-Term Incentive Plan, filed as Appendix B to the Definitive Proxy Statement on Schedule 14A filed on May 25, 2016, and incorporated herein by reference.*
- 10.1(b) Amendment to Amended and Restated 2003 Long-Term Incentive Plan, filed as Appendix B to the Definitive Proxy Statement on Schedule 14A filed on May 25, 2016, and incorporated herein by reference.*
- 10.1(c) Amended and Restated Form of Stock Option Agreement under the 2003 Long-Term Incentive Plan for Robert J. Coury, Heather Bresch, and Rajiv Malik, filed by Mylan Inc. as Exhibit 10.2 to Form 10-Q for the quarter ended September 30, 2013, and incorporated herein by reference.*
- 10.1(d) Amended and Restated Form of Stock Option Agreement under the 2003 Long-Term Incentive Plan for awards granted following fiscal year 2012, filed by Mylan Inc. as Exhibit 10.4(i) to Form 10-K for the fiscal year ended December 31, 2013, and incorporated herein by reference.*
- 10.1(e) Form of Stock Option Agreement under the 2003 Long-Term Incentive Plan for Robert J. Coury, Heather Bresch, and Rajiv Malik for awards granted after February 27, 2015, filed as Exhibit 10.1(i) to Form 10-K for the fiscal year ended December 31, 2015, and incorporated herein by reference.*
- 10.1(f) Form of Restricted Stock Unit Award Agreement under the 2003 Long-Term Incentive Plan for Heather Bresch and Rajiv Malik for awards granted after February 27, 2015, filed as Exhibit 10.1(j) to Form 10-K for the fiscal year ended December 31, 2015, and incorporated herein by reference.*
- 10.1(g) Form of Performance-Based Restricted Stock Unit Award Agreement under the 2003 Long-Term Incentive Plan for Heather Bresch and Rajiv Malik for awards granted after February 27, 2015, filed as Exhibit 10.1(k) to Form 10-K for the fiscal year ended December 31, 2015, and incorporated herein by reference.*
- 10.1(h) Form of Stock Option Agreement under the 2003 Long-Term Incentive Plan for awards granted after February 27, 2015, filed as Exhibit 10.1(l) to Form 10-K for the fiscal year ended December 31, 2015, and incorporated herein by reference.*
- 10.1(i) Form of Restricted Stock Unit Award Agreement under the 2003 Long-Term Incentive Plan for awards granted after February 27, 2015, filed as Exhibit 10.1(m) to Form 10-K for the fiscal year ended December 31, 2015, and incorporated herein by reference.*
- 10.1(j) Form of Performance-Based Restricted Stock Unit Award Agreement under the 2003 Long-Term Incentive Plan for awards granted after February 27, 2015, filed as Exhibit 10.1(n) to Form 10-K for the fiscal year ended December 31, 2015, and incorporated herein by reference.*
- 10.1(k) Amendment to Amended and Restated 2003 Long-Term Incentive Plan, adopted as of February 23, 2017, filed as Exhibit 10.1 to Form 10-Q for the quarter ended March 31, 2017, and incorporated herein by reference.*
- 10.1(l) Form of Restricted Stock Unit Award Agreement under the 2003 Long-Term Incentive Plan for Heather Bresch and Rajiv Malik for awards granted on or after February 23, 2017, filed as Exhibit 10.2 to Form 10-Q for the quarter ended March 31, 2017, and incorporated herein by reference.*
- 10.1(m) Form of Performance-Based Restricted Stock Unit Award Agreement under the 2003 Long-Term Incentive Plan for Heather Bresch and Rajiv Malik for awards granted on or after February 23, 2017, filed as Exhibit 10.3 to Form 10-Q for the quarter ended March 31, 2017, and incorporated herein by reference.*
- 10.1(n) Form of Performance-Based Restricted Stock Unit Award Agreement under the 2003 Long-Term Incentive Plan for Heather Bresch and Rajiv Malik for awards granted on or after February 21, 2018, filed as Exhibit 10.2 to Form 10-Q for the quarter ended March 31, 2018, and incorporated herein by reference.*
- 10.1(o) Form of Performance-Based Restricted Stock Unit Award Agreement under the 2003 Long-Term Incentive Plan for awards granted on or after February 21, 2018, filed as Exhibit 10.3 to Form 10-Q for the quarter ended March 31, 2018, and incorporated herein by reference.*
- 10.2(a) Mylan Inc. Severance Plan, amended as of August, 2009, filed by Mylan Inc. as Exhibit 10.6 to Form 10-Q for the quarter ended September 30, 2009, and incorporated herein by reference.*
- 10.2(b) Amendment to Mylan Inc. Severance Plan, dated July 13, 2014, filed by Mylan Inc. as Exhibit 10.1 to Form 10-Q for the quarter ended September 30, 2014, and incorporated herein by reference.*

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- 10.3(a) Retirement Benefit Agreement, dated December 31, 2004, between Mylan Inc. and Robert J. Coury, filed by Mylan Inc. as Exhibit 10.7 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.*
- 10.3(b) Amendment to Retirement Benefit Agreement, dated April 3, 2006, between Mylan Inc. and Robert J. Coury, filed by Mylan Inc. as Exhibit 10.11(b) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.*
- 10.3(c) Amendment to Retirement Benefit Agreement, dated December 22, 2008, between Mylan Inc. and Robert J. Coury, filed by Mylan Inc. as Exhibit 10.20(c) to Form 10-K for the fiscal year ended December 31, 2008, and incorporated herein by reference.*
- 10.3(d) Amendment to Retirement Benefit Agreement, dated March 3, 2010, by and between Mylan Inc. and Robert J. Coury, filed by Mylan Inc. as Exhibit 10.1 to Form 8-K filed with the SEC on March 5, 2010, and incorporated herein by reference.*
- 10.3(e) Amendment to Retirement Benefit Agreement, effective as of January 1, 2012, by and between Mylan Inc. and Robert J. Coury, filed by Mylan Inc. as Exhibit 10.6 to Form 8-K filed with the SEC on October 28, 2011, and incorporated herein by reference.*
- 10.3(f) Amendment to Retirement Benefit Agreement, effective as of January 1, 2014, by and between Mylan Inc. and Robert J. Coury, filed by Mylan Inc. as Exhibit 10.2 to the Report on Form 8-K filed with the SEC on February 28, 2014, and incorporated herein by reference.*
- 10.4 Retirement Benefit Agreement, dated August 31, 2009, by and between Mylan Inc. and Heather Bresch filed by Mylan Inc. as Exhibit 10.3 to Form 10-Q for the quarter ended September 30, 2009, and incorporated herein by reference.*
- 10.5 Retirement Benefit Agreement, dated August 31, 2009, by and between Mylan Inc. and Rajiv Malik, filed by Mylan Inc. as Exhibit 10.4 to Form 10-Q for the quarter ended September 30, 2009, and incorporated herein by reference.*
- 10.6 Form of Retirement Benefit Agreement Waiver Letter by and between Mylan Inc. and certain executive officers of Mylan Inc., filed by Mylan Inc. as Exhibit 10.58 to Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.*
- 10.7(a) Transition and Succession Agreement, dated December 15, 2003, between Mylan Inc. and Robert J. Coury, filed by Mylan Inc. as Exhibit 10.19 to Form 10-Q for the quarter ended December 31, 2003, and incorporated herein by reference.*
- 10.7(b) Amendment No. 1 to Transition and Succession Agreement, dated December 2, 2004, between Mylan Inc. and Robert J. Coury, filed by Mylan Inc. as Exhibit 10.1 to Form 10-Q for the quarter ended December 31, 2004, and incorporated herein by reference.*
- 10.7(c) Amendment No. 2 to Transition and Succession Agreement, dated April 3, 2006, between Mylan Inc. and Robert J. Coury filed by Mylan Inc. as Exhibit 10.19(c) to Form 10-K for the fiscal year ended March 31, 2006, and incorporated herein by reference.*
- 10.7(d) Amendment No. 3 to Transition and Succession Agreement, dated December 22, 2008, between Mylan Inc. and Robert J. Coury, filed by Mylan Inc. as Exhibit 10.25(d) to Form 10-K for the fiscal year ended December 31, 2008, and incorporated herein by reference.*
- 10.8(a) Amended and Restated Transition and Succession Agreement, dated December 31, 2007, between Mylan Inc. and Heather Bresch, filed by Mylan Inc. as Exhibit 10.2 to Form 10-Q for the quarter ended March 31, 2008, and incorporated herein by reference.*
- 10.8(b) Amendment No. 1 to Transition and Succession Agreement, dated December 22, 2008, between Mylan Inc. and Heather Bresch, filed by Mylan Inc. as Exhibit 10.27(b) to Form 10-K for the fiscal year ended December 31, 2008, and incorporated herein by reference.*
- 10.9(a) Transition and Succession Agreement, dated January 31, 2007, between Mylan Inc. and Rajiv Malik, filed by Mylan Inc. as Exhibit 10.5 to Form 10-Q for the quarter ended March 31, 2008, and incorporated herein by reference.*

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Amendment No. 1 to Transition and Succession Agreement, dated December 22, 2008, between Mylan Inc. 10.9(b) and Rajiv Malik, filed by Mylan Inc. as Exhibit 10.28(b) to Form 10-K for the fiscal year ended December 31, 2008, and incorporated herein by reference.*

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- 10.10(a) Transition and Succession Agreement, dated February 25, 2008, by and between Mylan Inc. and Anthony Mauro, filed by Mylan Inc. as Exhibit 10.5(a) to Form 10-Q for the quarter ended March 31, 2012, and incorporated herein by reference.*
- 10.10(b) Amendment No. 1 to Transition and Succession Agreement, dated December 15, 2008, by and between Mylan Inc. and Anthony Mauro, filed by Mylan Inc. as Exhibit 10.5(b) to Form 10-Q for the quarter ended March 31, 2012, and incorporated herein by reference.*
- 10.10(c) Amendment No. 2 to Transition and Succession Agreement, dated October 15, 2009, by and between Mylan Inc. and Anthony Mauro, filed by Mylan Inc. as Exhibit 10.5(c) to Form 10-Q for the quarter ended March 31, 2012, and incorporated herein by reference.*
- 10.11 Form of Transition and Succession Agreement Waiver Letter by and between Mylan Inc. and certain executive officers of Mylan Inc., filed by Mylan Inc. as Exhibit 10.57 to Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.*
- 10.12 Transition and Succession Agreement, dated April 27, 2016 and effective June 6, 2016, between Mylan Inc. and Kenneth S. Parks, filed as Exhibit 10.3 to Form 10-Q for the quarter ended June 30, 2016, and incorporated herein by reference.*
- 10.13 Transition and Succession Agreement, dated March 24, 2017, between Mylan Inc. and Daniel M. Gallagher, filed as Exhibit 10.6 to Form 10-Q for the quarter ended March 31, 2017, and incorporated herein by reference.*
- 10.14(a) Mylan 401(k) Restoration Plan, dated January 1, 2010, filed by Mylan Inc. as Exhibit 10.1 to the Report on Form 8-K filed by Mylan Inc. with the SEC on December 14, 2009, and incorporated herein by reference.*
- 10.14(b) Amendment to Mylan 401(k) Restoration Plan, dated November 4, 2014, filed by Mylan Inc. as Exhibit 10.41(b) to Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.*
- 10.15(a) Mylan Executive Income Deferral Plan, filed by Mylan Inc. as Exhibit 10.2 to the Report on Form 8-K filed with the SEC on December 14, 2009, and incorporated herein by reference.*
- 10.15(b) Amendment to Mylan Executive Income Deferral Plan, dated November 4, 2014, filed by Mylan Inc. as Exhibit 10.42(b) to Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.*
- 10.16 The Executive Nonqualified Excess Plan Adoption Agreement, effective as of December 28, 2007, between Mylan International Holdings, Inc. and Rajiv Malik, filed by Mylan Inc. as Exhibit 10.27(b) to Form 10-K for the fiscal year ended December 31, 2013, and incorporated herein by reference.*
- 10.17 The Executive Nonqualified Excess Plan, effective as of December 28, 2007, between Mylan International Holdings, Inc. and Rajiv Malik, filed by Mylan Inc. as Exhibit 10.57 to Form 10-K for the fiscal year ended December 31, 2013, and incorporated herein by reference.*
- 10.18 Third Amended and Restated Executive Employment Agreement, entered into on February 25, 2014, by and between Mylan Inc. and Robert J. Coury, filed by Mylan Inc. as Exhibit 10.1 to the Report on Form 8-K filed with the SEC on February 28, 2014, and incorporated herein by reference.*
- 10.19(a) Second Amended and Restated Executive Employment Agreement, entered into on February 25, 2014, by and between Mylan Inc. and Heather Bresch, filed by Mylan Inc. as Exhibit 10.3 to the Report on Form 8-K filed with the SEC on February 28, 2014, and incorporated herein by reference.*
- 10.19(b) Extension No. 1, dated November 3, 2018 to the Second Amended and Restated Executive Employment Agreement, entered into on February 25, 2014, by and between Mylan Inc. and Heather Bresch.*
- 10.19(c) Third Amended and Restated Executive Employment Agreement, entered into on February 25, 2019, and effective as of April 1, 2019, by and between Mylan Inc. and Heather Bresch.*
- 10.20(a) Second Amended and Restated Executive Employment Agreement, entered into on February 25, 2014, by and between Mylan Inc. and Rajiv Malik, filed by Mylan Inc. as Exhibit 10.4 to the Report on Form 8-K filed with the SEC on February 28, 2014, and incorporated herein by reference.*

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- 10.20(b) Extension No. 1, dated November 3, 2018 to the Second Amended and Restated Executive Employment Agreement, entered into on February 25, 2014, by and between Mylan Inc. and Rajiv Malik.*
- 10.20(c) Third Amended and Restated Executive Employment Agreement, entered into on February 25, 2019 2019, and effective as of April 1, 2019, by and between Mylan Inc. and Rajiv Malik.*
- 10.21(a) Amended and Restated Executive Employment Agreement, dated January 8, 2016 and effective January 1, 2016, by and between Mylan Inc. and Anthony Mauro, filed as Exhibit 10.16 to Form 10-K for the fiscal year ended December 31, 2015, and incorporated herein by reference.*
- 10.21(b) Executive Employment Agreement, dated as of February 25, 2019, and effective as of April 1, 2019, by and between Mylan Inc. and Anthony Mauro.*
- 10.22(a) Executive Employment Agreement, dated April 27, 2016 and effective June 6, 2016, between Mylan Inc. and Kenneth S. Parks, filed as Exhibit 10.2 to Form 10-Q for the quarter ended June 30, 2016, and incorporated herein by reference.*
- 10.22(b) Executive Employment Agreement, dated as of February 25, 2019, and effective as of April 1, 2019, by and between Mylan Inc. and Kenneth S. Parks.*
- 10.23(a) Executive Employment Agreement, dated March 24, 2017 and effective April 1, 2017, between Mylan Inc. and Daniel M. Gallagher, filed as Exhibit 10.5 to Form 10-Q for the quarter ended March 31, 2017, and incorporated herein by reference *
- 10.23(b) Consulting Agreement, entered into on February 25, 2019, by and between Mylan Inc. and Daniel M. Gallagher.*
- 10.24 Letter Agreement, entered into on November 4, 2014, by and between Mylan Inc. and Robert J. Coury, filed by Mylan Inc. as Exhibit 10.59 to Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.*
- 10.25 Letter Agreement, dated June 3, 2016, among Mylan N.V., Mylan Inc., and Robert J. Coury, filed as Exhibit 10.5 to Form 10-Q for the quarter ended June 30, 2016, and incorporated herein by reference.*
- 10.26(a) Form of Performance-Based Stock Appreciation Rights Award Agreement under the Mylan Inc. One-Time Special Five-Year Performance-Based Realizable Value Incentive Program, filed by Mylan Inc. as Exhibit 10.5 to the Report on Form 8-K filed with the SEC on February 28, 2014, and incorporated herein by reference.*
- 10.26(b) Form of Performance-Based Restricted Stock Unit Award Agreement under the Mylan Inc. One-Time Special Five-Year Performance-Based Realizable Value Incentive Program, filed by Mylan Inc. as Exhibit 10.6 to the Report on Form 8-K filed with the SEC on February 28, 2014, and incorporated herein by reference.*
- 10.27(a) Form of One-Time Special Five-Year Performance-Based Realizable Value Incentive Program Waiver Letter with respect to Stock Appreciation Rights, by and between Mylan Inc. and certain executive officers of Mylan Inc., filed by Mylan Inc. as Exhibit 10.56(a) to Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.*
- 10.27(b) Form of One-Time Special Five-Year Performance-Based Realizable Value Incentive Program Waiver Letter with respect to Performance Based Restricted Stock Units, by and between Mylan Inc. and certain employees of Mylan Inc., filed by Mylan Inc. as Exhibit 10.56(b) to Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.*
- 10.27(c) Form of Performance-Based Restricted Stock Unit Award Agreement under the One-Time Special Five-Year Performance-Based Realizable Value Incentive Program for Kenneth S. Parks, filed as Exhibit 10.66 to Form 10-K for the fiscal year ended December 31, 2016, and incorporated herein by reference.*
- 10.27(d)

Form of Performance-Based Restricted Stock Unit Award Agreement under the One-Time Special Five-Year Performance-Based Realizable Value Incentive Program for Daniel M. Gallagher, filed as Exhibit 10.7 to Form 10-Q for the quarter ended March 31, 2017, and incorporated herein by reference. *

10.28 Form of Waiver Letter with respect to Specified Award Agreements by and between Mylan N.V. and Heather Bresch and Rajiv Malik, February 23, 2017, filed as Exhibit 10.4 to Form 10-Q for the quarter ended March 31, 2017, and incorporated herein by reference. *

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- 10.29 Supplemental Health Insurance Program For Certain Officers of Mylan Inc., effective May 1, 2005.* Amended and Restated Form of Indemnification Agreement between Mylan Inc. and each Director, filed by
- 10.30 Mylan Inc. as Exhibit 10.38 to Form 10-K for the fiscal year ended December 31, 2013, and incorporated herein by reference.*
- 10.31 Form of Indemnification Agreement between Mylan N.V. and each Director, filed as Exhibit 10.1 to the Report on Form 8-K filed with the SEC on February 27, 2015, and incorporated herein by reference.*
- 10.32 Call Option Agreement between Mylan N.V. and Stichting Preferred Shares Mylan, dated April 3, 2015, filed as Exhibit 10.1 to the Report on Form 8-K filed with the SEC on April 3, 2015, and incorporated herein by reference.
- 10.33(a) Revolving Credit Agreement, dated November 22, 2016, among Mylan N.V., Mylan Inc., as a guarantor, the lenders and issuing banks party thereto and Bank of America, N.A., as the administrative agent, filed as Exhibit 10.62 to Form 10-K for the fiscal year ended December 31, 2016, and incorporated herein by reference.
- 10.33(b) Amendment, dated as of November 3, 2017, to the Revolving Credit Agreement dated as of November 22, 2016, among Mylan N.V., certain affiliates and subsidiaries of Mylan N.V. from time to time party thereto as guarantors, each lender from time to time party thereto, each issuing bank from time to time party thereto and Bank of America, N.A., as administrative agent, filed as Exhibit 10.3 to the Form 10-Q for the quarter ended September 30, 2017, and incorporated herein by reference.
- 10.34(a) Revolving Credit Agreement, dated as of July 27, 2018, among Mylan Inc., as borrower, Mylan N.V., as a guarantor, the other guarantors party thereto, certain lenders and issuing banks and Bank of America, N.A., as administrative agent, filed as Exhibit 10.1 to the Report on Form 8-K filed with the SEC on July 30, 2018, and incorporated herein by reference.
- 10.34(b) Amendment No. 1, dated February 22, 2019, to the Revolving Credit Agreement dated as of July 27, 2018, among Mylan Inc., as borrower, Mylan N.V., as a guarantor, the other guarantors party thereto, certain lenders and issuing banks and Bank of America, N.A., as administrative agent.
- 10.35(a) Term Credit Agreement, dated November 22, 2016, among Mylan N.V., Mylan Inc., as a guarantor, the lenders party thereto and Goldman Sachs Bank USA, as administrative agent, filed as Exhibit 10.63 to Form 10-K for the fiscal year ended December 31, 2016, and incorporated herein by reference.
- 10.35(b) Amendment, dated as of November 3, 2017, to the Term Credit Agreement dated as of November 22, 2016, among Mylan N.V., certain affiliates and subsidiaries of Mylan N.V. from time to time party thereto as guarantors, each lender from time to time party thereto and Goldman Sachs Bank USA, as administrative agent, filed as Exhibit 10.4 to the Form 10-Q for the quarter ended September 30, 2017, and incorporated herein by reference.
- 10.35(c) Amendment No. 2, dated as of February 22, 2019, to the Term Credit Agreement dated as of November 22, 2016, among the Company, certain affiliates and subsidiaries of the Company from time to time party thereto as guarantors, each lender from time to time party thereto and Goldman Sachs Bank USA, as administrative agent.
- 10.36 Guarantee Agreement, dated as of December 22, 2016, among Meda AB (publ), Mylan N.V. and AB Svensk Exportkredit (publ), filed as Exhibit 10.64 to Form 10-K for the fiscal year ended December 31, 2016, and incorporated herein by reference.
- 10.37 Guarantee, dated December 20, 2016, by Mylan N.V. of Meda AB (publ)'s obligations under the 2013/2018 SEK 600,000,000 floating rate notes and 2014/2019 SEK 750,000,000 floating rate notes issued by Meda AB (publ), filed as Exhibit 10.65 to Form 10-K for the fiscal year ended December 31, 2016, and incorporated herein by reference.
- 10.38 Form of Dealer Agreement among Mylan N.V., Mylan Inc. and the Dealer thereto, filed as Exhibit 10.1 to the Report on Form 8-K filed with the SEC on June 8, 2017, and incorporated herein by reference.
- 10.39 Form of Dealer Agreement among Mylan N.V., Mylan Inc. and the Dealer thereto, filed as Exhibit 10.2 to the Report on Form 8-K filed with the SEC on July 30, 2018, and incorporated herein by reference.

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| <u>10.40</u> | Settlement Agreement with the U.S. Department of Justice and two relators finalizing the Medicaid drug rebate settlement, dated August 16, 2017, filed as Exhibit 10.1 to the Report on Form 8-K filed with the SEC on August 21, 2017, and incorporated herein by reference. |
| <u>10.41</u> | Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Mylan Inc. and Mylan Specialty L.P., dated August 16, 2017, filed as Exhibit 10.2 to the Report on Form 8-K filed with the SEC on August 21, 2017, and incorporated herein by reference. |
| <u>10.42</u> | Registration Rights Agreement, dated as of April 9, 2018, among Mylan Inc., Mylan N.V., as guarantor, and Deutsche Bank Securities Inc., J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC, as representatives of the initial purchasers of the Notes, filed as Exhibit 10.1 to the Report on Form 8-K filed with the SEC on April 9, 2018, and incorporated herein by reference. |
| <u>21.1</u> | Subsidiaries of the registrant. |
| <u>23</u> | Consent of Independent Registered Public Accounting Firm. |
| <u>31.1</u> | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| <u>31.2</u> | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| <u>32</u> | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase |

*Denotes management contract or compensatory plan or arrangement.

Exhibits and schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish
^ a copy of any omitted exhibits and schedules to the Securities and Exchange Commission upon request but may request confidential treatment for any exhibit or schedule so furnished.

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SIGNATURES

Pursuant to the requirements of section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Form to be signed on its behalf by the undersigned, thereunto duly authorized on February 26, 2019.

Mylan N.V.

by /s/ HEATHER BRESCH
 Heather Bresch
 Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Form has been signed below by the following persons on behalf of the registrant and in the capacities indicated as of February 26, 2019.

| Signature | Title |
|--|--|
| /s/ HEATHER BRESCH Heather Bresch | Chief Executive Officer and Director (Principal Executive Officer) |
| /s/ KENNETH S. PARKS Kenneth S. Parks | Chief Financial Officer (Principal Financial Officer) |
| /s/ PAUL B. CAMPBELL Paul B. Campbell | Senior Vice President and Chief Accounting Officer (Principal Accounting Officer) |
| /s/ ROBERT J. COURY Robert J. Coury | Chairman and Director |
| /s/ ROBERT J. CINDRICH Robert J. Cindrich | Director |
| /s/ JOELLEN LYONS DILLON JoEllen Lyons Dillon | Director |
| /s/ NEIL DIMICK Neil Dimick | Director |
| /s/ MELINA HIGGINS Melina Higgins | Director |
| /s/ HARRY A. KORMAN Harry A. Korman | Director |
| /s/ RAJIV MALIK Rajiv Malik | President and Director |
| /s/ MARK W. PARRISH Mark W. Parrish | Director |
| /s/ RANDALL L. VANDERVEEN, PH.D. Randall L. Vanderveen, Ph.D. | Director |

/s/ PAULINE VAN DER MEER MOHR Director
Pauline van der Meer Mohr

/s/ SJOERD S. VOLLEBREGT Director
Sjoerd S. Vollebregt

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